Choice Framework for local Policy and Procedures (CFPP) 01-01
Management and decontamination of surgical instruments (medical devices) used in acute care

Part A: The formulation of local policy and choices
Preface

Introduction
The Choice Framework for local Policy and Procedures (CFPP) is an initiative being piloted by the Department of Health.

It forms a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.

Purpose
The purpose of CFPP is to enable local choices to be made regarding the management, use and decontamination of reusable medical devices at controlled costs using risk control.

CFPP is designed to reflect the need to continuously improve outcomes in terms of:
- patient safety;
- clinical effectiveness; and
- patient experience.

Essential Quality Requirements and Best Practice
The Health Act Code of Practice recommends that healthcare organisations comply with guidance establishing Essential Quality Requirements and demonstrate that a plan is in place for progression to Best Practice.

Essential Quality Requirements (EQR), for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. EQRs incorporate requirements of the current Medical Devices Directive and Approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute provider operates safely with respect to its decontamination services.

Local policy should define how a provider achieves risk control and what plan is in place to work towards Best Practice.

Best Practice is additional to EQR. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; promote and encourage innovation and choice; and achieve cost efficiencies.

Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses guidance on the whole of the decontamination cycle, including, for example, improved instrument management, where there is evidence that these procedures will contribute to improved clinical outcomes.

The CFPP suite is listed below.
- Choice Framework for local Policy and Procedures 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care
- Choice Framework for local Policy and Procedures 01-04: Decontamination of linen for health and social care
- Choice Framework for local Policy and Procedures 01-06: Decontamination of flexible endoscopes
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Geoff Sjogren Institute of Decontamination Sciences
Geoffrey L. Ridgway, OBE, MD Clinical Microbiologist
Graham Stanton NHS Wales Shared Services Partnership – Facilities Services
Helen Baxter University of Edinburgh
Jackie Duggan Health Protection Agency
James Ironside University of Edinburgh
Jim Gray Birmingham Children’s Hospital NHS Foundation Trust
Jimmy Walker Health Protection Agency
Ken Toal Health Estates, Northern Ireland
Margaret Hollis Great Ormond Street Hospital
Mike Painter Public Health Physician
Mike Simmons Public Health Wales
Peter Brigham Newcastle upon Tyne Hospitals NHS Foundation Trust
Peter Hoffman Health Protection Agency
Robert Baxter University of Edinburgh
Robert Kingston IHEEM Decontamination Technology Platform
Sylvia Martin University College Hospital London
Terry Durack Great Ormond Street Hospital
Tracy Coates Association for Perioperative Practice
Abbreviations

ACDP-TSE RM [subgroup]: Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies Risk Management [subgroup] (formerly the TSE Working Group)

ACDST: Advisory Committee on Decontamination Science and Technology

AE(D): Authorising Engineer (Decontamination)

AP(D): Authorised Person (Decontamination)

BCH: Birmingham Children’s Hospital

BS: British Standard

BSE: Bovine Spongiform Encephalopathy

CFPP: Choice Framework for local Policy and Procedures

CJD: Creutzfeldt-Jakob disease

CMO: Chief Medical Officer

CP(D): Competent Person (Decontamination)

CQC: Care Quality Commission

DH: Department of Health

DIPC: Director of Infection Prevention and Control

EDIC: episcopic differential interference contrast

EDIC/EF: episcopic differential interference contrast/epifluorescence

EFSCAN: epifluorescent surface scanner

EN: European norm

FITC: fluorescein isothiocyanate

GOSH: Great Ormond Street Hospital

ISO: International Standards Organisation

MDD: Medical Devices Directive

MDR: Medical Devices Regulations

MHRA: Medicines and Healthcare products Regulatory Agency

NDS: National Decontamination Survey

NICE: National Institute for Health and Clinical Excellence


OPA/NAC: o-phthalaldehyde/N-acetyl-L-cysteine

PO: posterior ophthalmic

sCJD: sporadic Creutzfeldt-Jakob disease

SSD: sterile services department

TSEs: transmissible spongiform encephalopathies

UCHL: University College Hospital London

vCJD: variant Creutzfeldt-Jakob disease
Choice Framework for local Policy and Procedures (CFPP) 01-01 offers best practice guidance on the whole decontamination cycle including the management and decontamination of surgical instruments used in acute care.

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. The technical concepts are based on European (EN), International (ISO) and British (BS) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

Part B covers common elements that apply to all methods of surgical instrument reprocessing such as:

- test equipment and materials
- design and pre-purchase considerations
- validation and verification.

Part C covers standards and guidance on steam sterilization.

Part D covers standards and guidance on washer-disinfectors.

Part E covers low temperature (non-steam) sterilization processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure).


CFPP 01-01 Parts B–E supersede Health Technical Memoranda 2010, 2031 and Health Building Note 13 Supplement 1, and partially supersede Health Technical Memorandum 2030. Only washer-disinfectors used for processing surgical instruments (and not those used in laboratories or for endoscopes) are covered in CFPP 01-01.
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Decontamination Lead
Designated Person
Surgical Instrument Manager/Coordinator
Senior Operational Manager
User
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Authorised Person (Decontamination) (AP(D))
Competent Person (Decontamination) (CP(D))
Director of Infection Prevention and Control (DIPC)
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Operator
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1 Introduction

1.1 Choice Framework for local Policy and Procedures (CFPP) is a suite of best practice guidance that is currently being piloted by the Department of Health (DH) for England. The framework is designed to reflect the need to improve efficiency and outcomes in terms of safety, clinical effectiveness and patient experience in line with health policy direction.

1.2 This CFPP offers best practice guidance on the management and decontamination of surgical instruments used in acute care. The guidance supports the ‘Health and Social Care Act 2008: Code of Practice for the prevention and control of infections and related guidance’ (2010 revision), and has been developed to strengthen local decision making and accountability. This CFPP also supports the vision for the NHS as set out in the Health and Social Care Act 2012.

1.3 In order to be registered with the Care Quality Commission (CQC), providers are required to maintain appropriate levels of cleanliness and hygiene in relation to reusable medical devices. The Code of Practice provides guidance on how providers can meet this registration requirement, including key recommendations on the provision of a safe decontamination service that generates a clean and sterile product.

1.4 The Health and Social Care Act 2012 sets out the Government’s intention to ensure providers are properly regulated, allowing them to work with clinical commissioners to focus on improving outcomes, be more responsive to patients and innovate.

1.5 The Act also introduces a duty on the NHS Commissioning Board and clinical commissioning groups to secure continuous improvement in the quality of outcomes achieved from health services. These outcomes are to focus on the effectiveness, safety and patient experience aspects of healthcare.

1.6 CFPP 01-01 supports local decision-making in the commissioning, regulation, management, use and decontamination of surgical instruments used in acute care. The guidance is designed to support continuous improvements in efficiency and outcomes in terms of safety, clinical effectiveness and patient experience by:

- guiding care commissioners and regulators in assessing the local policies and practices of a provider in terms of their approach to the management and decontamination of surgical instruments. Clear definitions of Essential Quality Requirements and Best Practice are provided in this CFPP, to help with this assessment;
- providing the evidence base and standards for use by providers of care and those decontaminating surgical instruments within the NHS or commercially, to support them in their decision-making process;
- contributing to the effective management of surgical instruments through all parts of the use and reprocessing cycle (see Figure 1). This includes management practices related to surgical instruments in the theatre environment;
- providing guidance for service-users and patient groups on issues that are relevant to them. This has been written to take account of HealthWatch’s future role in working with providers, commissioners and quality regulators;
- using the experience of recent pilot studies to demonstrate new approaches to risk management and to the implementation of the National Institute for Health and Clinical Excellence’s (NICE) interventional procedure guidance 196 – ‘Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures’ (hereafter referred to as NICE IPG 196 (2006)). (See Appendix A: ‘Reports from DH pilot studies concerning the implementation of NICE IPG 196 (2006) guidance’.)
1.7 With CFPP 01-01, the DH is seeking to establish:

- the prevention and control of the risk of transmission of infection through surgical instruments – with specific reference to the theoretical risk of human prion diseases transmission (transmissible spongiform encephalopathies, or TSEs);
- a comprehensive approach to risk control and reduction across instrument management and decontamination;
- assurance over the management of surgical instruments, in terms of availability, quality and suitability;
- the preservation and advance of high-quality engineering through the support of European Norms (ENs), quality systems and standards;
- guidance for optimisation of the environment, equipment and facilities used in surgical decontamination.

1.8 CFPP 01-01 refers to NICE IPG 196 (2006) and guidance derived from the Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies Risk Management (ACDP-TSE RM) subgroup (formerly the TSE Working group) throughout. It draws on the findings of the National Decontamination Survey (NDS) (2008–2010) to highlight aspects of decontamination management practice that need addressing, and presents findings from NDS pilot studies to suggest ways in which decontamination management practices can be developed.

1.9 Management recommendations centre on:

- improving instrument set integrity
- ensuring that a separate pool of new neuroendoscopes and reusable surgical instruments is available for high risk procedures on patients born since 1 January 1997, as it is thought that people born since 1 January 1997

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**Note**

Regulators include the CQC, the Medicines and Healthcare products Regulatory Agency (MHRA), and notified bodies.
have had lower exposure to prions via the food chain or blood transfusion;

- ensuring contingency for dropped or unavailable instruments;
- ensuring a continuously moist environment for instruments between use and reprocessing;
- ensuring maximum efficiency in protein removal (see Appendix A: ‘Reports from DH pilot studies concerning the implementation of NICE IPG 196 (2006) guidance’);
- having a system in place for surgical instrument management and to cover the quality, condition and suitability of reusable surgical instrument.

1.10 Whether decontamination services are provided by the healthcare provider or from an external source, the requirements of the instrument management and decontamination policy outlined in this guidance should be followed.


**Structure of CFPP 01-01**

1.12 CFPP 01-01 Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment.

1.13 The technical concepts are based on European (EN), International (ISO) and British (BS) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

1.14 Part B covers common elements that apply to all methods of surgical instrument reprocessing such as:

- test equipment and materials
- design and pre-purchase considerations
- validation and verification.

1.15 Part C covers standards and guidance on steam sterilization.

1.16 Part D covers standards and guidance on washer-disinfectors.

1.17 Part E covers low temperature (non-steam) sterilization processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure).
2 Decontamination policy for reusable surgical instruments

2.1 A safe decontamination service contributes to successful clinical outcomes and the wellbeing of patients and staff. Healthcare providers in England are required by law to comply with essential levels of safety and quality which are assessed by the CQC. These levels are set in law through registration requirements, one of which covers cleanliness and infection control. Guidance on meeting this registration requirement is provided by the ‘Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance’. The Code of Practice recommends that healthcare organisations comply with guidance establishing Essential Quality Requirements and demonstrate that a plan is in place for progression to Best Practice.

2.2 CFPP 01-01 draws on DH policy and current advice to provide comprehensive guidance on the management and decontamination of surgical instruments used in acute care. This includes clear definitions of what constitutes Essential Quality Requirements and Best Practice.

2.3 In acute care, precautionary policies in respect of human prion diseases including vCJD also apply.

2.4 This guidance therefore seeks to offer advice across a range of risk types. Specifically, these include:

- The risk of infection via surgical instruments.
- The theoretical but potentially highly significant risk of transmission of human prion diseases including, but not limited to, vCJD.
- The availability, quality and suitability of surgical instruments.
- Interruption to, or abandonment of, surgery where this is due to instrument quality, the absence of key instruments from the surgical set or, in very rare instances, where an instrument has been dropped perioperatively or otherwise has had its sterility compromised during use.

2.5 In this CFPP, a number of options are offered for dealing with risks highlighted by the NDS (2008–2010). These options are outlined based on experience gained from pilot studies and guidance, and include information on the observed outcomes. As experience grows, individual reports and findings will be incorporated.

2.6 See Appendix B: The National Decontamination Survey report.

The policy context

2.7 CFPP 01-01 is best practice guidance, which has been developed from the following policy initiatives.

2.8 The Health and Social Care Act 2012 sets out the framework for the government’s vision for modernising the NHS. It gives power to clinicians to make commissioning decisions, and gives more choice and control to patients. It also establishes Monitor as a strong service regulator to act in the interests of patients.

2.9 The NHS Commissioning Board will continue to look to providers to deliver services that enhance patient safety and the patient experience, and that deliver value for money. Part of this is a drive towards constant assurance of correctly selected, clean, sterile and fully functioning surgical instruments at the point of care delivery.

2.10 The management and decontamination of surgical instruments are key components in the delivery of safe interventional care. This guidance advocates a full assessment of the volume and types of surgical service provided, the turnaround times required for decontamination, the prion transmission risks associated with the tissues encountered in each area of service, and the instrument stock required for onsite and offsite decontamination. To gain a full understanding of the risks involved, including the risk of prion disease transmission, see paragraph 5.1, ‘Risk from prion diseases’.

2.11 In light of this, CFPP 01-01 advocates that commissioners, providers and regulators adopt a risk-control approach to the management of single-
use instruments and to the management and decontamination processes for reusable surgical instruments, in line with the essential requirements of the Medical Devices Directive (MDD) and the ENs that support them (see Chapter 4, 'Regulatory framework').

**Essential Quality Requirements and Best Practice in decontamination**

2.12 **Essential Quality Requirements**, for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. Essential Quality Requirements incorporate requirements of the current MDD and approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute care service provider operates safely with respect to the management and decontamination of instruments.

2.13 Attainment of Essential Quality Requirements should also include a local risk-assessment for surgical instrument management, encompassing the provision of instruments that are safe to use and the reliable provision of all required instruments.

2.14 Local policy should define how a provider achieves risk control and what plan is in place to work towards Best Practice.

2.15 Local policy development that takes account of this CFPP guidance could result in amended theatre practices, such as improvements to the audit trail for instruments and the provision of instruments sets that do not require the use of supplementary instruments (for example, see Appendix A paragraph A45).

2.16 Comparison of local policy statements and quality systems with audit results will confirm attainment of Essential Quality Requirements and progression towards Best Practice. Such assessment could provide a mechanism for differentiating between care providers in commissioning services.

2.17 **Best Practice** is additional to the Essential Quality Requirements. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; promote and encourage innovation and choice; and achieve cost efficiencies.

2.18 Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses guidance on the whole of the decontamination cycle, including, for example, improved instrument management, where there is evidence that these procedures will contribute to improved clinical outcomes.

**Developing a decontamination policy**

2.19 In the context of this CFPP, decontamination policy is dependent on the types of surgical procedure undertaken and determined by the staff involved with the management and decontamination of reusable surgical instruments. It is recommended that staff conduct a local risk assessment, record their local policy, and adopt and develop procedures appropriate to their services. The policies and procedures selected should meet Essential Quality Requirements or exceed them by achieving Best Practice. Figure 2 illustrates the drivers for improvements and desired outcomes.

2.20 This applies to decontamination facilities on and off healthcare premises and in decontamination services managed by independent healthcare providers.

2.21 For the key elements of a decontamination policy, see paragraph 4.25, ‘The Health and Social Care Act 2008: Code of Practice’.

**Local determination of Best Practice**

2.22 To assess Best Practice, a local risk assessment group may be set up. This group could assess decontamination option requirements and consider what aspects of Best Practice should be implemented, based on improving patient outcomes, decontamination benefits, efficiencies and risks, including those prion risks as defined by the ACDP-TSE Risk Assessment subgroup.

2.23 A Director of Infection Prevention and Control (DIPC) will have ultimate responsibility for the risk assessments. Others included in the group could be:

- the DIPC’s designated appointee;
- the decontamination lead;
- the surgical instrument manager;
- representative(s) from the Infection Control Team;
- representative(s) from the clinical device users;
- the User;
• an Authorising Engineer (Decontamination).

2.24 For a brief summary of staffing roles and responsibilities, see paragraph 6.34, ‘Staffing roles and responsibilities’.

2.25 Others, such as representatives of decontamination services and estates and facilities, may be members of the group or co-opted at the discretion of the DIPC.

Implementation of CFPP 01-01

2.26 This guidance will help providers to achieve a satisfactory level of risk control together with compliance with the essential requirements of the Medical Devices Regulations (MDR).

2.27 This guidance recommends that all providers of surgical care work with their decontamination specialists to achieve Essential Quality Requirements and a locally risk-assessed progression to Best Practice. Not all service providers will be in a position to adopt Best Practice recommendations. However, every service provider will need to:

• assess what Best Practice is appropriate for each of the decontamination settings in their control, based of the surgical procedures undertaken;
• what improvements they need to undertake to move towards these; and
• prepare a plan for progression to Best Practice.

2.28 All units where surgical instruments are used or decontaminated should be working at or above Essential Quality Requirements and have in place local policies and business development programmes that demonstrate progression to Best Practice.

2.29 This guidance has been developed and validated by a series of pilot studies in England and Scotland, which looked primarily at the feasibility and practicality of implementation. The lessons learned form an important part of this CFPP (see ‘Examples of local choice’, following).

Examples of local choice

2.30 DH-funded pilot studies have been active in addressing a number of key risk-reduction alternatives. Principally these include:

• Maintaining instruments in a moist environment following use and before reprocessing.
• The retention of surgical instruments within their sets by the application of both individual instruments and set level track and trace technologies.
• Revision of set contents in neurosurgery in order to obtain enhanced suitability for purpose.
2.31 The following pilot-study summaries are provided as possible examples of local choice (for the full reports, see links in each section).

**Keeping instruments moist and protein quantification using o-phthalaldehyde/ N-acetyl-L-cysteine (OPA/NAC) fluorescence**

2.32 This collaboration between Great Ormond Street Hospital (GOSH), University College Hospital London (UCLH) and Queen Mary University of London aimed to investigate several aspects of instrument management and decontamination. These included implementation of NICE IPG 196 (2006) guidance on reducing instrument migration and separate pooling of instruments for patients born after 1 January 1997, keeping instruments moist prior to reprocessing, research into enhanced protein detection, and optimisation of washer-disinfector performance.

2.33 NICE IPG 196 (2006) guidance has been successfully implemented through the introduction of single-instrument tracking and tray level tracing, via GS1 coding and matrix marking of instruments with scanning at various points throughout the use/reprocessing cycle. This has also enabled effective segregation of new instruments for patients born after 1 January 1997, supported by protocols to determine who may have access to these instruments.

2.34 An OPA/NAC fluorescence-based digital image capture system has been developed that provides increased sensitivity and quantification of residual protein on reprocessed instruments. This system has demonstrated a five-order of magnitude improvement in protein removal when moist, compared with test pieces allowed to dry after use. Experiments with different washer-disinfector chemistries and item positions show that there is considerable variation in efficacy associated with both variables. See Appendix A paragraph A2, ‘Keeping instruments moist and protein quantification using OPA/NAC fluorescence’.

**Revision of instrument set: design and management**

2.35 This pilot was undertaken at Newcastle upon Tyne Teaching Hospitals NHS Trust to investigate the prevention of migration of neurosurgical instruments between sets using single-instrument tracking via GS1 coding. However, initial trials were cumbersome and indicated that there were high levels of instrument leakage occurring, possibly connected to high levels of supplementary instrument use. The project was therefore revised to focus on the suitability of the instrument sets for the intended surgery.

2.36 A substantial revision to set contents resulted in fewer but larger instrument sets and has largely eliminated the need for supplementary instruments. Where sets have become too large for easy handling, they have been split among multiple caskets with GS1 coding employed to track at tray and set level, with some selective use of individual instrument tracking. As a result, instrument leakage has dropped to negligible levels. Colour-coded casket lids distinguish high-risk sets from general sets as well as those sets reserved for patients born after 1 January 1997. These techniques are supported by audit procedures and have proven simple to administer and robust in practice. See Appendix A paragraph A45, ‘Revision of instrument set: design and management’.

**Single instrument tracking and management using a commercial decontamination services provider**

2.37 The Birmingham Children’s Hospital NHS Trust has been working with its decontamination services provider to implement NICE IPG 196 (2006) guidance in the context of an external commercial decontamination service contract. The key aspects addressed are limitation of instrument migration through single-instrument tracking of neurosurgical instruments and the maintenance of separate instrument sets for patients born after 1 January 1997.

2.38 Instruments have been uniquely marked with matrix codes that relate to GS1 identifiers, though there are issues over the durability of these marks.
on some of the smaller instruments where the code has to be restricted to a very small area. Software upgrades have been put in place to support the single-instrument tracking; protocols for its use have been developed by both the trust and the decontamination services provider. Tracking of the instruments will also enable tracing to patients (within the trust only), enhancing a manual paper-based system.

2.39 New sets of neurosurgical instruments for patients born after 1 January 1997 have been purchased and marked. An identification system, involving colour coding of the handles of each instrument in these sets, had been explored but has not been implemented on microbiological advice. The set labelling also included the text: “post 1997”. See Appendix A paragraph A65, ‘Single-instrument tracking and management using a commercial decontamination service provider’.

Protein quantification using epifluorescence scanning

2.40 A sensitive fluorescence-based scanning technique developed at the University of Edinburgh allows analysis of reprocessed surgical instruments from the Royal Infirmary of Edinburgh to be assessed for the distribution and concentration of protein.

2.41 The compact bench-top scanner unit, driven by a standard PC, is suitable for use in a sterile services department (SSD). A combination of measurements from instruments provided by the Royal Infirmary were used to develop a “traffic light” system to enable SSD staff to accept scanned instruments as being clean and fit for reuse. Comparisons against a visual validation process used with washer–disinfectors have been carried out. Further software development of the user interface, particularly in respect of presenting “hot spot” contamination information, plus scanning optimisation is ongoing, as is work on establishing both current ranges of protein contamination on surgical instruments and target ranges for improved decontamination processes. See Appendix A paragraph A85, ‘Protein quantification using epifluorescence scanning’.

Protein quantification using episcopic differential interference contrast (EDIC)/epifluorescence microscopy

2.42 Work using a novel microscope-based fluorescence technique, developed by the University of Southampton, has enabled sensitive measurement of general proteins and specifically “plaque” proteins associated with vCJD on reprocessed surgical instruments than can be detected using established swab-based tests. This technique correlates with other studies to show that visual assessment of the contamination on reprocessed instruments can be extremely inaccurate.

2.43 Tests on commercial chemistries used in SSD washer-disinfectors have shown that none are fully effective against protein contamination and that there is a wide range of efficacy between products. Tests on surgical instruments passing through the SSD at Southampton General Hospital are in progress and will provide more detailed information about the effectiveness of the process, in parallel with conventional testing. See Appendix A paragraph A97, ‘Protein quantification using EDIC/epifluorescence microscopy’.
3 Guidance for commissioners, regulators and providers

3.1 The overarching aim of the commissioning function is to ensure the highest levels of patient care and staff safety, in the most cost-effective manner. In commissioning decontamination services for surgical instruments used in acute care, commissioning organisations should aim to deliver:

- sustainable high standards of patient safety;
- improved clinical care outcomes arising from a carefully considered local instrument management strategy;
- an enhanced patient experience through minimising delay and procedure cancellations associated with instrument provision;
- cost efficiencies from instrument provision to the demands of the care given;
- local choice in the means of risk control both through instrument management and in choices with regard to decontamination;
- appropriate quality systems and engineering standards;
- professional work by trained managers and staff throughout the reusable surgical instrument cycle.

See the NHS Operating Framework 2012/13 for further guidance on the new commissioning and management system for the NHS.

3.2 Responsibility for achieving acceptable standards of decontamination rests with commissioning organisations, individual trusts and provider organisations. Reprocessing units in healthcare establishments responsible for the decontamination of medical devices fall into two distinct categories when considering compliance with the MDD:

- Devices transferred between legal entities (for example – reprocessing and use by the same entity or organisation).

For further information, see paragraph 4.5, ‘Compliance with the Medical Devices Regulations’.

3.3 When commissioning surgery, commissioning organisations should require that the healthcare provider is receiving devices, or it has a decontamination service, that meets the essential requirements of the MDR and is able to demonstrate evidence of an appropriate quality management system and audit system.

3.4 Commissioning organisations should also expect the healthcare provider to have a plan in place to achieve Best Practice. This plan should have been developed, having taken account of the risk of surgical procedures (see paragraph 2.19, ‘Developing a decontamination policy’ and Chapter 5, ‘The evidence base: The risk from prion disease and findings from the National Decontamination Survey’). Commissioning organisations may use this plan to improve the services commissioned from providers for the benefit of patients, and to differentiate between providers.

3.5 They may do this by:

- including the attainments within the service specification element of the standard contract;
- establishing key performance indicators as part of a tendering process; and
- using Best Practice as an incentive to improve provider performance.

3.6 Best Practice could also be used as attainment levels against which improvements can be measured and rewarded, enabling commissioners to encourage evidence-based practices and innovation.

3.7 Providers may refer to paragraph 2.12, ‘Essential Quality Requirements and Best Practice in decontamination’ in order to assess the quality of
their decontamination services and demonstrate quality improvement within their organisation.

3.8 In the event of poor performance, commissioners may discuss the level of performance with their providers and address any issues and concerns before introducing more formal contractual remedies.

3.9 Regulators may use the recorded risk-assessed local policy to check Essential Quality Requirements attainments alongside adherence to regulatory requirements.

**Implication for contractual agreements**

3.10 The adoption of a risk-control based approach to surgical instrument management should not prejudice current contractual agreements. While there is sufficient flexibility in current contractual arrangements to accommodate the CFPP approach, the development of local policies and procedures may require locally negotiated variations to the contract to accommodate changes to the service specification. There are two routes to vary the contracts let through the National Decontamination Programme: via schedule 11 and schedule 21 of the Decontamination Services Agreement. For other third-party contracts, advice would have to be sought locally on the mechanism for implementing changes.

**Implication for third-party providers**

3.11 Where decontamination services are provided by a third party, all parties to the service should work together to develop local policies and procedures that are appropriate and can be implemented.

3.12 It should be noted that third-party providers of decontamination services come under the MDD (directive 93/42/EEC has been superseded by directive 2007/47/EC). They will be using existing British and European Standards to demonstrate compliance with the essential requirements of the MDD and will have a quality system against which they are independently audited. The development and implementation of new local policies and procedures may require a variation to the contract and changes to quality systems to accommodate.
4 Regulatory framework

4.1 This chapter sets out the duty of care for decontamination services in England. The regulatory framework is applicable across all sectors of healthcare (see Figure 3).

**Figure 3** Overview of the interaction between the different structures within the English legislative system

**English Legislation (this is not an exclusive list)**
- Health and Social Care Act 2010–2012
- Health and Social Care Act 2008 (Regulated Activities Regulations 2010
- Health Act 2009
- Health and Safety at Work etc Act 1974
- Consumer Protection Act 1997
- Health and Social Care (Community Health and Standards) Act 2003

**British, European and International Standards**
- Medical Devices Regulations 2002
- Pressure Systems Safety Regulations 2000 (as amended)
- Control of Substances Hazardous to Health Regulations 2002 (as amended)
- Personal Protective Equipment at Work Regulations 1992 (as amended)
- The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance

**Notes**
1. The In-Vitro Diagnostic Devices and Active Implantable Medical Devices Directives have been included for completeness although these devices are usually supplied sterile and are single-use.
European legislation

4.2 There are three EU Directives relating to the manufacture and supply of medical devices:

- MDD 93/42/EEC
- Active Implantable Medical Devices Directive 90/385/EEC.

4.3 These three directives have been transposed into UK law as the Medical Devices Regulations (MDR) 2002, as amended. (For more information about the MDDs and compliance, visit the MHRA’s website.)

4.4 Washer-disinfectors and sterilizers – that is, those machines specifically intended for the decontamination of reusable medical devices – can also fall within the scope of the MDR.

Compliance with the Medical Devices Regulations

4.5 Only those units that transfer reusable medical devices between legal entities are within the scope of the MDD and the MDR.

4.6 Devices decontaminated for reuse within the same legal entity or trust are not “placed on the market” and are therefore outside the scope of the regulations.

4.7 Irrespective of this, however, the standards applied to all organisations that provide decontamination services are monitored against the essential requirements of the MDD. This is undertaken either by a notified body, whose activities are monitored by the MHRA if the formal certification route is applied, or by the CQC.

4.8 Figure 4 illustrates the regulatory framework and the compliance routes for reusable medical devices transferred between legal entities and for reusable medical devices remaining within one legal entity.

Compliance with the MDD

4.9 Responsibility for achieving acceptable standards of decontamination rests with commissioners, individual trusts and provider organisations.

4.10 Healthcare organisations decontaminating reusable medical devices fall into two distinct categories when considering compliance with the MDD:

- reusable medical devices transferred between legal entities
- reusable medical devices remaining within one legal entity

Figure 4 Regulation and audit of decontamination services and the respective responsibilities of MHRA and CQC
• reusable medical devices remaining within one legal entity.

4.11 The requirement for formal certification of SSDs under the MDD is dependent on whether “product” is “placed on the market”. Providing products to another legal entity is “placing product on the market”.

4.12 The implications of the MDD regulations are that all those organisations that provide decontamination services and which “place product on the market” are legally required to demonstrate compliance to the harmonised standards contained within the directive. It provides a standardised approach to decontamination in the UK and across all European countries.

4.13 The most commonly used route to demonstrating compliance is to institute a quality management system such as BS EN ISO 13485 across all areas of the decontamination cycle.

4.14 BS EN ISO 13485 specifies requirements for a quality management system that can be used by a healthcare organisation for the design and development, production, installation and servicing of reusable medical devices and the design, development and provision of related services. It can also be used by internal and external parties, including certification bodies, to access the healthcare organisation’s ability to meet customer and regulatory requirements. Its primary objective is to facilitate reusable medical device regulatory requirements for quality management systems.

Reusable medical devices transferred between legal entities

4.15 Healthcare organisations offering the decontamination of reusable medical devices to another legal entity are subject to the requirements of the MDR. If sterile devices are produced, the intervention of a third-party audit programme must also be undertaken by a recognised notified body.

4.16 A notified body is a certification organisation that the competent authority (MHRA within the UK) designates to carry out one or more of the conformity assessment procedures described in the annexes of the MDR.

4.17 Healthcare organisations “placing product on the market” must also register with the MHRA.

4.18 Commissioners should be provided access, if required, to check that a provider is registered with a notified body and has an appropriate quality system in place.

4.19 Commissioners should be given access to the results of the most recent third-party (notified body) audit and should be able to see any:

• non-conformances picked up in the audit;
• required corrective actions that have been agreed; and
• evidence of corrective actions being implemented.

Reusable medical devices remaining within one legal entity

4.20 If a healthcare organisation only provides decontaminated reusable medical devices for use on, or by, patients of that same entity (that is, there is no “placing on the market”), the MDR do not apply.

4.21 These healthcare organisations do not need to register with the MHRA nor do they need to use a notified body; nevertheless, they are subject to the duty of care imposed under product liability. They must still ensure instruments are safe, fit for purpose and of suitable quality. The CQC will assess the performance of these organisations. Registration with the CQC includes a number of requirements in this area, and providers are required to comply with these requirements.

4.22 Compliance with BS EN ISO 13485 will demonstrate a commitment to producing reusable medical devices of appropriate quality.

Outsourcing

4.23 The options for those healthcare organisations that do not undertake decontamination services include:

• Using a decontamination service that is registered with the MHRA, that is compliant with the MDR, and that uses a notified body as its third-party auditor.
• Using CE-marked single-use medical devices.

4.24 The relative merits of the options should be evident through developing a business case highlighting the options, timescales, cost benefits and reliability assessment.
The Health and Social Care Act 2008: Code of Practice

4.25 The guidance provided here is consistent with the ‘Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance 2010 revision’ (‘the Code’). The Code recommends that effective prevention and control of healthcare-associated infections be embedded in everyday practice. For this reason, the guidance is written with emphasis on practical and readily implemented measures.

4.26 Adhering to this CFPP will assist providers in complying with the decontamination guidance set out in the Code and in meeting the CQC registration requirement on hygiene and infection control.

Key Code recommendations

4.27 With a view to minimising the risk of infection, a registered provider should normally ensure that it designates leads for environmental cleaning and decontamination of equipment used for diagnosis and treatment (a single individual may be designated for both areas).

4.28 The decontamination lead should have responsibility for ensuring that policies exist and that they take account of best practice and national guidance for the decontamination of reusable surgical instruments.

4.29 The decontamination policy should demonstrate that:

- it complies with guidance establishing Essential Quality Requirements and a plan is in place for progression to Best Practice;
- decontamination of reusable medical devices takes place in appropriate facilities designed to minimise the risks that are present;
- appropriate procedures are followed for the acquisition, maintenance and validation of decontamination equipment;
- staff are trained in cleaning and decontamination processes and hold appropriate competences for their role; and
- a record-keeping regime is in place to ensure that decontamination processes are fit for purpose and use the required quality systems.

(See also Outcome 11, Regulation 16 Safety, availability and suitability of equipment contained in CQC Guidance about compliance.)

Registration with the Care Quality Commission

4.30 The Care Quality Commission (CQC) regulates all providers of regulated health and adult social care activities in England.

4.31 The CQC’s role is to provide assurance that the care given meets essential requirements of quality and safety.

4.32 The registration requirements are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and include requirements relating to:

- safety and suitability of premises;
- safety, availability and suitability of equipment; and
- cleanliness and infection control.

4.33 The CQC is responsible for developing and consulting on its methodology for assessing whether providers are meeting the registration requirements (see the CQC’s Guidance about compliance (2010)). Failure to comply with the requirements is an offence, and under the 2008 Act, CQC has a wide range of enforcement powers that it can use if the provider is not compliant. These include the issue of a warning notice that requires improvement within a specified time, prosecution, and the power to cancel a provider’s registration, removing its ability to provide regulated activities.

British, European and International Standards

4.34 To support the MDD and to assist manufacturers (including decontamination services) to interpret the essential requirements, the European Commission has published an updated list of harmonised standards. Compliance with all relevant harmonised standards on this list leads to an automatic presumption that the medical devices comply with the requirements of the MDD.

4.35 Although compliance with a mandated standard is not the only way of complying with the directives, it is the simplest.

4.36 The list of standards given in Appendix D is not exhaustive but includes the key documents that
may be used to inform the management of decontamination of reusable medical devices in a healthcare organisation. See also the website of the European Union.

**Policy and guidance**

4.37 The DH and other professional bodies and advisory committees have published guidance on the decontamination of surgical instruments. The list below is not exhaustive but includes the key resources that may be used to inform the management of decontamination within a health service environment:

- The DH’s CFPP series.
- For a list of medical device alerts, safety notices, hazard notices and device bulletins relating to decontamination, visit the MHRA’s website.

4.38 The DH’s policy is that the measures defined in NICE IPG 196 (2006) guidance be incorporated into practice and supplemented by the guidance derived from the ACDP-TSE RM subgroup:

- ACDP-TSE RM provides practical scientifically based advice on the management of risks from TSEs in order to limit or reduce the risks of human exposure to, or transmission of, TSEs in healthcare and other occupational settings.
- NICE IPG 196 (2006) provides guidance on how best to manage the risk of transmission of CJD and vCJD via interventional procedures. This was the subject of CMO Letters recommending the implementation of NICE IPG 196 (2006) and is DH policy.
5 The evidence base: the risk from prion diseases and findings from the National Decontamination Survey

Risk from prion diseases

5.1 Management and decontamination of surgical instruments policy and supporting guidance is closely linked to reducing or preventing the risk of transmission of prion diseases.

5.2 Prion diseases are rare, fatal, degenerative conditions of the central nervous system (brain and spinal cord) that affect humans and certain other animals. Until 1986 few people had heard of them but that changed with the appearance of Bovine Spongiform Encephalopathy (BSE) or mad cow disease.

5.3 In 1996 it was confirmed that BSE had been transmitted to humans via contaminated beef products. This was a new condition in humans and was called vCJD.

5.4 This name was chosen to differentiate the new condition from sporadic CJD (sCJD), a very rare human prion disease that had been known for nearly a century and which usually affects people aged over 60 years.

5.5 So far there have been fewer than 200 cases of vCJD diagnosed in the UK, with smaller numbers in other countries. In contrast to sCJD, the median age at onset of vCJD is only 28 years.

5.6 Although some cases of CJD seem to occur spontaneously, it is possible to infect laboratory animals by inoculating them with brain tissue taken from another infected animal or source of human infection. BSE and other prion diseases have also been shown to be transmissible in this way. Some of this experimentation involves the use of CJD contaminated test wires or spheres that are used to model surgical instruments and are made from the same materials.

5.7 As a result of the above properties, CJDs are often referred to as TSEs.

5.8 A very small number of cases of sCJD have occurred following procedure using surgical instruments (including electrodes) that had previously been used in surgery on the brain of someone subsequently shown to be suffering with CJD. This occurred despite the instruments having been decontaminated and sterilized using conventional methods. This is because the infectious agent believed to cause prion diseases (a misfolded or abnormal version of a normal cellular protein PrP) is very hard to destroy.

5.9 Some forms of CJD are hereditary, meaning that they are passed down from generation to generation, and some occur because of genetic mutations. There is an even rarer human prion disease called Gerstmann-Sträussler-Scheinker disease (GSS), which is a genetic condition and causes a condition very similar to sCJD.

5.10 A key feature of prion diseases is that they can have extensive incubation periods after exposure to the infectious agent, sometimes measured in years.

5.11 In recent years a number of cases of vCJD have occurred in patients who received blood transfusions from donors who themselves later went on to develop vCJD. To date all those patients tested, with one possible exception, have homozygous MM DNA bases at Codon 129 of the PrP gene. Thus there may be a link between susceptibility and genetic status.

5.12 To summarise, prion diseases are rare but fatal. They affect the brain. They can occur spontaneously; be hereditary; or can occur as a result of genetic mutation. They are caused by an agent that is very hard to destroy. They can be transmitted from one animal (including humans) to another by inoculation.

5.13 The DH takes a precautionary approach in this area of disease transmission. That is, the risk of prion transmission should be minimised within the constraints of current knowledge.
Why is there such concern about prion diseases?

5.14 So far, the number of known transmissions of prion disease from one human to another is very small. CJD in its classical (or sporadic) form is the most common of the human TSEs, but it is still rare, with an annual incidence worldwide of around one case per million population (Hilton and Ironside, 2003).

5.15 However, vCJD differs from sCJD and the other human prion diseases in two important areas:
- Significant infectivity can be found in tissues other than the brain.
- Surveys suggest that many thousands of people might be symptom-free but infected.

5.16 Since it was first described there have been over 170 deaths from definite or probable cases of vCJD in the UK. The peak year for deaths was 2000, since when numbers of cases per annum have fallen but not ceased.

5.17 Currently, there is no reliable screening test that can be used to identify people infected with vCJD, though research is ongoing, neither is a cure available.

5.18 This, plus the fact that standard methods of decontaminating surgical instruments cannot reliably fully deactivate or destroy the infectious agent causing the disease, raises the possibility that vCJD could be transmitted via certain healthcare interventions.

5.19 The DH’s precautionary principle, to ensure that the risk of prion transmission is minimised within the constraints of current knowledge, underpins much of what is contained in this guidance.

Prion diseases and surgical instruments

5.20 The abnormal protein that occurs in prion diseases accumulates in various tissues.

5.21 In both sCJD and vCJD the highest levels occur in the central nervous system (intradural operations on the brain, that is brain, spinal cord and intracranial sections of cranial nerves) in people who are showing symptoms of the disease. The tissues at the back of the eye (for example, the retina) also have high levels of abnormal protein. These are all referred to as ‘high-risk tissues’.

5.22 In vCJD, lower but significant levels occur in lymphoid tissues earlier in the disease process and, crucially, before any symptoms are apparent. These are referred to as ‘medium-risk tissues’.

5.23 The abnormal protein is heat-stable, exceptionally resistant to enzymatic digestion and, once dried onto instrument surfaces, very difficult to remove or inactivate by conventional reprocessing.

5.24 This means that special measures are required to prevent the potential transmission of all forms of prion disease from one patient to the next as a result of surgery that employs reusable instruments.

5.25 Patients who have been diagnosed as having a prion disease who are undergoing surgery present a possible hazard to other patients. In addition, a number of people have been categorised as being ‘at-risk’ for prion disease by an expert committee called the CJD Incidents Panel.

5.26 Guidance has been produced by the ACDP-TSE RM subgroup to help healthcare providers identify and manage these groups of patients. This guidance is signposted throughout the CFPP.

5.27 Extra vigilance is required to ensure that appropriate decontamination measures are in place when a patient who has been diagnosed as having a prion disease or who is considered to be ‘at risk’ undergoes surgery on high-risk tissues. Extra vigilance is therefore required for ophthalmic surgery and intradural operations on the brain.

5.28 The risk of transmission via reusable surgical instruments is the subject of periodic review.

5.29 The guidance in this framework has been developed to support acute surgery in the context of risk control, especially where instruments would come into contact with high-risk tissues.

Use of instruments on patients at risk of infection from prion diseases

5.30 Patients who have, probably have, or are at risk of infection from prion diseases (for example, sCJD and vCJD) need to be identified before any surgical procedures are undertaken. For such patients, precautions will need to be considered. Guidance from ACDP-TSE RM and the CJD Incidents Panel should be followed (see links in the References section).
5.31 Key points to note are:

- Guidance should be in place locally to ensure that precautions are taken when dealing with such patients.
- The traceability system for equipment used on such patients is very important. Also, its subsequent storage or use must be recorded and the advice of the CJD Incidents Panel should be obtained.
- Surgical instruments used on high-risk or medium-risk tissue in an infected patient, designated infected patient or patient designated at increased risk of CJD/vCJD should be retained for use on that same patient after conventional decontamination as defined in this framework, or destroyed by incineration.
- Depending on the patient's risk factors, and the type of procedure to be carried out, it may be necessary to quarantine the equipment pending further investigation.
- Some reusable items may need to be disposed of as they cannot be cleaned to the required standard. Advice should be sought from the Microbiologist (Decontamination).

Summary for commissioners and regulators

5.32 Commissioners should establish whether the local policies in use by care providers involving surgical instruments draw clear attention to the need for risk control with regard to potential exposure of instruments to the vCJD infectious agent.

5.33 Regulators should pay particular regard to this area of risk control when examining management structures, operational processes, the content and maintenance of records and material indicative of prion risk control outcomes.

5.34 Care providers and instrument management/decontamination groups should prioritise attention to vCJD risk control on a cohesive basis, backed by local policies and procedures that have been agreed with commissioners of care.

5.35 Guidance from the ACDP-TSE RM subgroup is available from their website.

Policy requirements for high prion transmission risk surgical instruments

5.36 In surgery to the central nervous system (intradural operations on the brain) and to the posterior eye, there is a comparatively high risk of prion transmission from the possible exposure of the instruments to the prion infectious agents including, but not limited to, vCJD.

5.37 DH policy is that the measures defined in NICE IPG 196 (2006) be incorporated into practice and supplemented by guidance derived from the ACDP-TSE RM subgroup.

5.38 The risk analysis associated with this implementation leads to the adoption of the Best Practice choices within this framework by centres providing relevant specialist surgical services, and should be acknowledged by commissioners in the purchase of care. The agreed approach should be recorded in a written local policy.

Assessing risk in surgical procedures

5.39 The levels of risk of CJD and vCJD transmission in surgical procedures are summarised below for the sake of clarity. These risks apply both to patients with clinical signs and symptoms of CJD and vCJD, and asymptomatic individuals who have been identified as being at increased risk of CJD and vCJD.

5.40 High-risk procedures: Procedures considered to be at high risk of transmission of all forms of CJD involve tissues with high levels of infectivity. These high infectivity tissues are those found in the central nervous system, spinal cord and the posterior eye. High-risk procedures include intradural neurosurgical operations (involving the brain, spinal cord and intracranial sections of cranial nerves), neuroendoscopy, and operations on the posterior eye (involving the retina or optic nerve).

5.41 Medium-risk procedures are those involving olfactory epithelium and spinal ganglia in patients with all forms of CJD. All procedures involving tonsils, spleen, lymph nodes, gastrointestinal lymphoid tissues (for example Peyers patches), thymus and the adrenal gland in patients with vCJD are considered to be medium risk.

5.42 Low-risk procedures are those other than the high- and medium-risk procedures.

5.43 A full list of tissue infectivity is available from Part 4 of ACDP-TSE RM’s guidance – ‘Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings’. The website of the CJD Incidents panel has further information on the classification of surgical instruments.
procures into high, medium and low risk procedures.

5.44 A full list of surgical procedures considered high-risk is given in NICE IPG 196 (2006) guidance.

5.45 A full list of ophthalmological surgical procedures designated high and low risk is given in ACDP-TSE RM's Annex L – ‘Managing CJD/vCJD risk in ophthalmology’.

Note
The assessment of whether an individual about to undergo a surgical procedure has, or is at increased risk of, CJD or vCJD should be done on an individual patient basis and responsibility for this lies with the clinical team. Guidance on the assessment to be carried out before surgery to identify patients with, or at increased risk of, CJD or vCJD, is available from ACDP-TSE RM’s Annex J – ‘Assessment to be carried out before surgery and/or endoscopy to identify patients with, or at increased risk of, CJD or vCJD’.

Findings from the National Decontamination Survey

5.46 The core purpose of the NDS was to determine the progress made by selected healthcare providers and decontamination service providers in implementing:

• NICE IPG 196 (2006) prion transmission risk reduction guidance; and

• ACDP-TSE RM guidance on specific risk control for patients at risk of CJD and vCJD.

5.47 In addition, the survey aimed to assess compliance with decontamination quality systems.

5.48 A site-visit based approach was used in both departments of surgery and their associated central sterilization services carried out by the Health Protection Agency, independent decontamination engineers and the acute trusts/service providers.

5.49 The survey comprised 30 centres offering neurosurgical and/or posterior ophthalmic services within both NHS and private institutions. The tissues involved in such surgery are high risk for prion disease and could lead to contamination of instrument such that they act as vectors of the infection to subsequent patients. The survey does not offer an overview of general surgical instrument decontamination.

5.50 The survey was carried out to inform risk estimates related to any further spread of human prions via surgical instruments. The survey findings were analysed using a figure-of-merit method, which is designed to emphasise progress and highlight risk-related omissions. The strategy used for interpretation of the data was developed with advice from the Engineering and Science Advisory Committee (ESAC), the ACDP-TSE Working Group.

Findings

5.51 The findings demonstrate that the great majority of centres are successfully implementing surgical instrument reprocessing quality system guidance, and that engagement with the guidance is likely to generate a positive impact on protein removal and prion infectivity reduction though this is yet to be demonstrated directly. However, the evidence also suggests that certain aspects of decontamination guidance are better followed than others, and that further development is needed to raise standards across all of the relevant areas.

5.52 The survey identified that NICE IPG 196 (2006) guidance had not been implemented fully. Migration of instruments between sets still occurs. Single instruments used to supplement sets of instruments are still used. Technologies that enable single instruments to be tracked, audited, retained in their sets and traced to use on individual patients are only implemented in a small number of centres. The introduction of a separate pool of instruments for use on high risk tissues for patients born after 1 January 1997 (a lower prion risk group) has been implemented only on a limited basis in a very few centres. The guidance from ACDP-TSE RM on surgical infection transmission risk control for at-risk patients was found to be well implemented.

5.53 The survey found that most staff were trained to an acceptable level in terms of the operation of the equipment they use, but that there is scope for broader training and professional development.

5.54 Single-use instruments are not common. However, reusable flexible neuroendoscopes are substantially replaced by single-use rigid endoscopes, reducing the risk in line with NICE guidelines.

5.55 The findings from this survey have been used to inform this CFPP.
6 Management of surgical instruments

Introduction

6.1 Evidence from the NDS identifies that certain aspects of decontamination guidance are better followed than others, and that further development is needed to raise standards across all of the relevant areas.

6.2 This chapter aims to provide further guidance on the management of surgical instruments to support further risk reduction and improvements to patient outcomes.

6.3 Management of surgical instruments in CFPP 01-01 relates to those used in acute care. In this context, management of surgical instruments should make sure that risks associated with surgical procedures are minimised.

6.4 The following management choices have been piloted in response to issues highlighted by the NDS:

• keeping instruments moist;
• separation of instruments used on high risk tissues for patients born before and after 1 January 1997;
• instrument audit and tracking.

6.5 Other management choices covered in this guidance include:

• loan sets;
• loan sets used in high-risk surgical procedures;
• repairs;
• instrument audit and tracking policy;
• single-use instrument tracking and records;
• decontamination of surgical instruments that have been dropped perioperatively.


Keeping instruments moist between use and reprocessing

6.7 Prions are hydrophobic proteins. The attachment of hydrophobic proteins to surfaces becomes less reversible if they are allowed to dry fully onto a surface. Keeping the environment around soiled instruments at or near saturation humidities (moist) prevents full attachment of hydrophobic proteins such that they are more efficiently removed by cleaning.

6.8 A number of means are available to generate moist conditions, including the use of enclosed containers/bagged trays used with single-use moist pads, gels, foams, water sprays or other methods as determined locally.

6.9 However, whatever method is used, care should be taken to ensure that all parts or surfaces of the surgical instruments are constantly exposed to the moist environment.

6.10 See Appendix A paragraph A2, ‘Keeping instruments moist and protein quantification using OPA/NAC fluorescence’.

Separation of instruments used on high risk tissues for patients born before and after 1 January 1997

6.11 It is thought that people born since 1 January 1997 have had lower exposure to prions via the food chain or blood transfusion. These people form a group at lower risk of prion diseases and thus at a lower risk of contaminating surgical instruments with prions. The NICE IPG 196 (2006) risk-reduction strategy requires that separate pools of instruments be used for high-risk tissue surgery, dependent on the patient’s birth date. This differentiates between patients who were either born before 1 January 1997, or who were born on or after 1 January 1997, and requires that separate pools of instruments be used for each stream.
6.12 If patients born on or after 1 January 1997 had high-risk surgery before the NICE guidance was implemented, subsequent high-risk tissue surgery shall be with instruments in the pre-1 January 1997 pool. For patients born after 1 January 1997 who have had previous high-risk tissue surgery using non-NICE IPG 196 (2006) controlled instruments, NICE IPG 196 (2006) recommends that any subsequent surgical procedures on these patients should be carried out using loan sets normally used for patients born before 1 January 1997. Figure 5 illustrates the pathway for associating patients with separate instrument pools. A method of ensuring that sets are used on the correct patient groups is clearly needed and should be such as to permit audit to confirm successful.

![Figure 5 Instrument pool identification for high-risk tissue surgery](image)

6.13 See Appendix A, paragraph A2, 'Keeping instruments moist and protein quantification using OPA/NAC fluorescence', paragraph A45, 'Revision of instrument set: design and management' and paragraph A65, 'Single-instrument tracking and management using a commercial decontamination service provider'.

**Loan sets**

6.14 For certain specialist procedures, there may be a need for instrument sets that it would be uneconomic for the provider to purchase and maintain. These will be supplied from an external source, used for that procedure only and returned. These are known as loan sets. This practice increases the risks associated with the decontamination and reprocessing of such instruments, because the organisation may not be familiar with them. Organisations have also expressed concern over the decontamination status of such instruments and the lack of track and traceability, including potential for instrument migration. It is a requirement of the Code of Practice that reusable medical devices should be decontaminated in accordance with manufacturers' instructions. Therefore, loan sets should be provided with decontamination instructions so that staff can ensure their compatibility with local decontamination processes. Set integrity needs to be maintained to minimise instrument migration and enable traceability to the patient. This extends to the control of individual instruments within loaned sets, to audit their removal and replacement.

**Loan sets used in high-risk surgical procedures**

6.15 Particularly for high-risk surgical procedures (see paragraph 5.39, 'Assessing risk in surgical procedures'), healthcare providers using loan sets should ensure that records of such sets are maintained within their control. These records should be available for independent review and should, at a minimum, make it possible to ascertain the details of the instruments contained within the set and the surgical units within which the set has been used. Dates and session times for each use should also be recorded. The identity of patients with whom the sets have been used should be traceable from the record but, for patient confidentiality, maintained within the secure environment of the clinical service providers concerned.

6.16 Instruments within loan sets shall be subject to quality system and control measures at least equal to those normally applied in the surgical centres where they are used. This applies equally when surgeons or other team members are the sponsor of any loan arrangement.

6.17 Theatre staff and SSDs should take special care to ensure integrity of loan sets and, for instruments used on high risk tissues, their membership of pre or post 1 January 1997 instrument groups from receipt to dispatch.

**Repairs**

6.18 Any instrument used on high risk tissues that are removed for repair should be returned to the instrument set from which it was removed.
Instrument audit and tracking

6.19 There is a need to track and trace reusable surgical instruments throughout their use and reprocessing. This is to avoid instrument migration and is an essential requirement of the MDR and the Code of Practice.

6.20 Records should be maintained for all the instrument sets (and supplementaries for high-risk procedures) identifying:
• the cleaning and sterilization method used
• a record of the decontamination equipment and cycle
• the identity of the person(s) undertaking decontamination at each stage of the cycle
• the patients on whom they have been used and details of the procedures involved.

6.21 This information is required so that instrument sets (and supplementaries for high-risk procedures) and the patients they have been used on can be traced and the instrument sets and supplementaries recalled when necessary.

6.22 The NDS shows that the use of single-instrument tracking and associated audit techniques remains under-used within hospitals in England. The maintenance and quality control of instruments was also shown to be poorly managed by the NDS survey information.

6.23 The reunification of instruments with their sets following repair or replacement benefits from accurate instrument identification. Tracking is likely to mitigate other factors, including those associated with operative failure due to the absence of key instruments or arising from poor adherence to scheduled instrument maintenance – particularly those which have electrical components.

6.24 For those instruments, including delicate components such as electronic devices or imaging related markers, the use of single instrument identification may be of special value. When marking is combined with properly managed decontamination procedures the individual instrument may be correctly identified as requiring a non-standard approach to washing, disinfection or sterilization.

6.25 Individual instruments may have warranties associated with them which carry a guarantee. However if the individual warranted instrument cannot be reliably identified to a standard which is satisfactory to the supplier, then it is unlikely that the warranty can be evoked. A similar argument applies to instruments such as arthroscopy scissors, which are limited in terms of the number of use cycles, authorised by the manufacturer under CE marking.

6.26 NICE IPG 196 (2006) guidance requires that high-risk tissue instrument sets used with patients born since 1 January 1997 form a pool within which instruments must be retained and from which other instruments must be excluded. This is challenging when supplementary instruments are used. Teams are likely to find effective streaming of non-marked instruments difficult. The use of larger sets which include supplementary instruments will partly mitigate this risk, particularly when combined with instrument marking, tracking and audit techniques.


Single-use instrument tracking and records

6.28 When single-use surgical instruments are used, they must be separated from reusable surgical instruments and disposed of at the end of the procedure. It is important that the single-use instruments are not allowed to enter reusable instrument sets.

Decontamination of surgical instruments that have been dropped perioperatively

6.29 Instruments dropped or which otherwise have their sterility compromised during use should be replaced. There should, where standard sets are being used, always be at least one readily accessible spare set so this can happen with minimal delay. The local policy to ensure this occurs efficiently should be established with the theatre users, the theatre manager and the DIPC (or their nominee). This may on rare occasions not be possible, for example if use of loan sets does not allow this.

6.30 On these occasions, a local risk assessment by the operating team should assess the relative risks of the options available, for example: the continuation of the procedure without that item; the abandonment
of surgery; the return of that item to the SSD for full decontamination.

6.31 Current DH policy remains to reduce inappropriate local reprocessing such as the use of non-compliant, non-validated bench top sterilizers. Development of local policies and procedures needs to consider benefits, risk and cost of the options available.

6.32 Where benchtop sterilizers are used these should be a last resort, and instruments should be subject to local manual cleaning to an agreed procedure. The unwrapped item should be processed in a downward displacement steam sterilizer maintained and validated including undertaking the necessary daily automatic control tests.

6.33 There should be measures in place to audit each use of this sterilizer and identify which cycles are for the sterilizer’s routine validation and which are for surgical instrument decontamination. This audit should ensure that the sterilizer is only used for instrument decontamination in the exceptional circumstances outlined above. It should be appreciated that this should be a last resort and should be reported through the hospital’s adverse incident report system.

6.37 Whatever model of operational management is chosen, the roles and responsibilities of the individuals involved should be clearly defined and documented. In every case, however, it should be possible to identify a User who is responsible for the day-to-day management of the decontamination of reusable surgical instruments. The philosophy of this CFPP is to invest the User with the responsibility for seeing that the decontamination process is operated safely and efficiently.

6.38 The following personnel are referred to in this CFPP.

**Management – definition**

6.39 Management of a healthcare organisation performing decontamination is defined as the owner, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises, including decontamination.

- Executive Manager (for example, chief executive);
- Decontamination Lead (this person may also act as the Designated Person if locally agreed);
- Designated Person
- Surgical Instruments Manager
- Senior Operational Manager (for example, estates manager);
- User (for example, sterile services manager);
- Authorising Engineer (Decontamination);
- Authorised Person (Decontamination);
- Competent Person (Decontamination);
- Director of Infection Prevention and Control (in England);
- Infection Control Doctor;
- Microbiologist (Decontamination);
- Operator;
- Manufacturer;
- Contractor;
- Purchaser;
- Competent Person (Pressure Systems).

**Staffing roles and responsibilities**

6.34 Staff undertaking decontamination and management of decontamination should be able to demonstrate their competencies and training in this area through:

6.35 Individual training records, detailing the appropriate core competencies and any other supplementary training, should be updated at least annually. Line or training managers should be responsible for maintaining these records.

6.36 The approach adopted in this CFPP is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual’s role in connection with decontamination but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with decontamination and in some cases the same individual may take on more than one role.
Executive Manager

6.40 The Executive Manager is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of personnel, for the organisation in which the decontamination equipment is installed.

6.41 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive or other person of similar authority.

Decontamination Lead

6.42 Every healthcare organisation should have a nominated Decontamination Lead with responsibility for decontamination, either at board level or who has line management responsibility to a senior responsible person at that level.

6.43 The Decontamination Lead should report directly to the Executive Manager.

6.44 The Decontamination Lead is organisationally responsible for the effective, and technically compliant, provision of decontamination services.

6.45 The Decontamination Lead is responsible for the implementation of an operational policy for decontamination. He/she should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment. The Decontamination Lead is also responsible for monitoring the implementation of the policy.

6.46 The Decontamination Lead may delegate specific responsibilities to key personnel; the extent of such delegation should be clearly set out in the operational policy together with the arrangements for liaison and monitoring.

6.47 The Decontamination Lead may also act as the Designated Person.

Designated Person

6.48 This person provides the essential senior management link between the organisation and professional support.

6.49 The Designated Person should also provide an informed position at board level.

6.50 The Designated Person should work closely with the Senior Operational Manager to ensure that provision is made to adequately support the decontamination system.

Surgical Instrument Manager/coordinator

6.51 The manager of surgical instruments (medical devices) is designated as the person assuming responsibility for coordinating activity between the theatre, decontamination and supply / purchase teams. The person fulfilling that role should also ensure that the inventory of surgical instruments is proactively reviewed and managed in accordance with this guidance, clinical requirements and industry best practice.

6.52 Specifically, this officer will:

- make judgements on the suitability of reusable instruments in consultation with surgical teams and those responsible for decontamination. This work will be assisted by the formation of a working group for ongoing collaboration;
- determine appropriate instrument-set structures designed to assist in the prevention of leakage of instruments between sets (including preventing the movement of supplementary instruments between sets) in consultation with clinical specialists and decontamination teams;
- ensure that guidance on tracking and traceability is appropriately applied to all instruments (this includes loan sets) and collaborate with those responsible for patient records to ensure any patient with whom they are used can be identified and linked to the sets or individual instruments used;
- ensure that missing or damaged surgical instruments are replaced preserving the appropriate set structure;
- oversee the monitoring of condition and suitability for surgical instruments;
- oversee the audit process for instrument sets from procurement through use, decontamination and final disposal;
- ensure instrument sets never used are reviewed and/or disposed of;
- oversee actions to provide a mechanism for routinely revalidating instrument-set content (for example, annual sign off of the tray checklist by surgical teams);
- ensure the leakage of surgical instruments between sets is minimized by effective process mapping using recommended audit procedures, post-operative checks, the signing of tray checklists by theatre sister, and decontamination...
facility processing techniques (that is, specific instrument set contents are kept together throughout the decontamination cycle);

- ensure instrument sets with observed missing or damaged content are updated through targeted investment ensure the healthcare organisation has documented policies in place for the operational management of its instrument-set inventory; these should include policies on (as a minimum);

- manage the loaning of instrument sets to and from external suppliers using the audit techniques given in this guidance;

- purchase new instrument and sets (including, as a minimum, the documented approval of the theatre team, decontamination specialists and Control of Infection lead);

- ensure repaired instruments are returned to the original instrument set;

- oversee a standardised approach to instrument nomenclature throughout the healthcare organisation;

- ensure all Instrument sets have an accurate version-controlled checklist validated by the surgical team (preferably in an electronic format);

- determine that all Instrument stores (including wards and departments) are audited on a regular basis, and all redundant items removed from circulation;

- ensure a mechanism is in place for addressing instrument set usage non-conformities such as wet packs, torn tray wrap etc.;

- provide and oversee mechanisms to ensure all instruments in the healthcare organisation’s inventory are fit for purpose (for example regular review of appropriate records);

- ensure the healthcare organisation holds an accurate database of its instrument-set inventory including tray type, location of use and stock level;

- ensure all instruments sets which are critical in stock levels are risk assessed, to maximize patient safety and inform instrument set investment.

**Senior Operational Manager**

6.53 The Senior Operational Manager is technically, professionally and managerially responsible (and accountable to the Decontamination Lead) for the engineering aspects of decontamination (for example, decontamination equipment and the environment).

**User**

6.54 The User is defined as the person designated by Management to be responsible for the management of the process. The User is also responsible for the Operators.

6.55 In the acute sector, the User could be a sterile services manager.

6.56 The principal responsibilities of the User are as follows:

- to certify that the decontamination equipment is fit for use;

- to hold all documentation relating to the decontamination equipment, including the names of other key personnel;

- to ensure that decontamination equipment is subject to periodic testing and maintenance;

- to appoint operators where required and ensure that they are adequately trained;

- to maintain production records;

- to establish procedures for product release in line with the quality management system;

- to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.

6.57 The User may seek the advice of infection control teams, which may consist of a DIPC, Infection Control Doctor or Microbiologist (Decontamination).

**Authorising Engineer (Decontamination) (AE(D))**

6.58 The role of the AE(D) should be fully independent of the healthcare facilities' structure for maintenance, testing and management of the decontamination equipment.

6.59 The AE(D) is defined as a person designated by Management to provide independent auditing and technical advice on decontamination procedures,
washed and disinfected, sterilized and sterilization and to review and witness documentation on validation.

6.60 The AE(D) is required to liaise closely with other professionals in various disciplines and, consequently, the appointment should be made known in writing to all interested parties.

6.61 The AE(D) should assist healthcare organisations in the appointments and interviews of the AP(D)s and their consequent annual assessments.

- The AE(D) should have a reporting route to the Decontamination Lead and should provide professional and technical advice to the AP(D)s, CP(D)s, Users and other key personnel involved in the control of decontamination processes in all healthcare facilities.

Responsibilities

6.62 The principal responsibilities of the AE(D) are as follows:

- to provide to Management and others, general and impartial advice on all matters concerned with decontamination;
- to advise Management and others on programmes of validation and testing;
- to audit reports on validation, revalidation and yearly tests submitted by the AP(D);
- to advise Management and others on programmes of periodic tests and periodic maintenance;
- to advise Management and others on operational procedures for routine production;
- to advise Management on the appointment of the AP(D);
- to provide technical advice on purchasing and selection of decontamination equipment for the users;
- to provide technical advice on the relevant guidance on decontamination equipment and procedures.

6.63 Each appointed AE(D) is independent in the advice and roles of the decontamination procedures and responsibilities for the effective management of the guidance and safety as recommended by the DH and regional administrations of Scotland, Wales and Northern Ireland.

The Institute of Healthcare Engineering and Estate Management (IHEEM) supports and operates the DTP (Decontamination Technology Platform) which is made up of IHEEM-registered AE(D)s (see link in the References section).

Authorised Person (Decontamination) (AP(D))

6.64 See ‘Responsibilities’ in CFPP 01-01 Part B.

Competent Person (Decontamination) (CP(D))

6.65 See ‘Responsibilities’ in CFPP 01-01 Part B.

Director of Infection Prevention and Control (DIPC)

6.66 The DIPC in England is defined as the person responsible for the infection control aspects of decontamination. The designated person is accountable directly to the Chief Executive and to the Board. If the person has a degree or equivalent qualification in microbiology, he/she may also fulfill the role of the Microbiologist (Decontamination).

Infection Control Doctor

6.67 The Infection Control Doctor is defined as a person designated by Management to be responsible for advising the User on all infection control aspects.

Microbiologist (Decontamination)

6.68 The Microbiologist (Decontamination) is designated by Management to be responsible for advising the User and that Management on microbiological and infection prevention aspects of the decontamination of reusable surgical instruments.

6.69 The Microbiologist (Decontamination) should have a relevant degree or equivalent qualification (for example, microbiology or medicine) together with relevant experience. In some organisations, the Microbiologist (Decontamination) and Infection Control Doctor may be the same person.

Operator

6.70 The Operator is defined as any person with the authority to operate decontamination equipment, including the noting of instrument readings and simple housekeeping duties.
6.71 Operators should have their tasks defined in their job description. Operators should also have documented training records to demonstrate that they are competent at undertaking their assigned tasks.

**Manufacturer**

6.72 See ‘Responsibilities’ in CFPP 01-01 Part B.

**Contractor**

6.73 See ‘Responsibilities’ in CFPP 01-01 Part B.

**Purchaser**

6.74 See ‘Responsibilities’ in CFPP 01-01 Part B.

### Competent Person (Pressure Systems)

6.75 The Competent Person as defined in the Pressure Systems Safety Regulations 2000 is not the same person as the Competent Person (Decontamination) defined in this CFPP. The former is a chartered engineer responsible for drawing up a written scheme of examination for the system. The latter is the person who carries out maintenance, validation and periodic testing of washer-disinfectors and sterilizers.

6.76 Most insurance companies maintain a technical division able to advise on appointing a CP(PS). The AE(D) should also be able to provide advice.
7 Inactivation of prions using novel technologies

7.1 A range of technologies that may be valuable in the inactivation of prions is becoming available. These technologies include: the use of proteolytic enzymes; strong alkaline solutions including sodium hydroxide; instrument exposure to cold plasmas; and high chemical activity gas or vapour agents such as ozone or activated hydrogen peroxide.

7.2 The issues surrounding efficacy and validation in regard to prion inactivation as a part of decontamination of surgical instruments are complex. Essentially, animal assays involving the exposure of rodent models to contaminated wires which have been subject to decontamination processes using the new technologies are key. These assays are in many cases very competently conducted and utilise well-designed methods incorporating vigorous controls. However, the range over which these assays permit measurements is restricted when compared to the potential scope of prion activity present as a contaminant.

Appendix A: Reports from DH pilot studies concerning the implementation of NICE IPG 196 (2006) guidance

Note
The views expressed in this Appendix are those of the editors and pilot study representative and not necessarily those of DH.

A1 The following DH-funded pilot studies have been active in addressing a number of key risk-reduction alternatives:
   • Keeping instruments moist and protein quantification using OPA/NAC fluorescence (a collaboration between GOSH, UCLH and Queen Mary University of London)
   • Revision of instrument set design and management (undertaken at Newcastle upon Tyne Teaching Hospitals NHS Trust)
   • Single instrument tracking using an external commercial decontamination services provider (the Birmingham Children’s Hospital NHS Trust in collaboration with its decontamination services provider)
   • Protein quantification using epifluorescence scanning (University of Edinburgh/Royal Infirmary of Edinburgh)
   • Protein quantification using EDIC/epifluorescence microscopy (University of Southampton)

Keeping instruments moist and protein quantification using OPA/NAC fluorescence
A2 Centres involved: GOSH/UCLH/Barts & Queen Mary University of London joint pilot studies.

Aims and objectives
A3 These multi-factorial linked studies, focused on prion risk reduction, set out to:
   • track instrument sets and single instruments to support the implementation of NICE IPG 196 (2006) guidance;
   • trial aspects of NICE IPG 196 concerned with the protection of patients born after 1 January 1997. This specifically includes the purchase of new instrument sets (GOSH) for high risk neurosurgical procedures, but not posterior ophthalmic, applications;
   • maintain contaminated instruments in a moist environment after use in for all neurosurgery procedures before reprocessing;
   • develop protocols for the use of a novel enhanced protein detection and quantification technology for assessment of neurosurgical instrument contamination after washing and disinfection.

Methods and approaches for each component of these studies
A4 Each of the objectives had written protocols developed by the hospitals’ senior decontamination staff:
   • Margaret Hollis (head of decontamination at GOSH)
   • Sylvia Martin (decontamination and sterile services manager at UCLH).
A5 They were assisted by Terry Durack (head nurse, clinical equipment, products and practice/co-chair clinical practice committee at GOSH) with support from the GOSH neurosurgical team, Elaine Cloutman-Green (clinical scientist at GOSH), and David Perrett (professor of bioanalytical science at Queen Mary University of London).
A6 The methodologies for each of the objectives were as follows:

1. Single-instrument and instrument set tracking
A7 Recommendation 1 of NICE IPG 196 (2006) was pursued through a combination of set component
2. New instrument sets for patients born after 1 January 1997

A13 The aspects of the pilot study concerned with procurement, quality control and use of new instrument sets for patients born after 1 January 1997 were taken forward after the single-instrument tracking methods were in place; otherwise migration between sets could have prejudiced any risk reduction.

A14 A review of instrument tray content was conducted in consultation with the surgical teams, led by the appropriate paediatric neurosurgeons. This produced modest revisions to the set contents, primarily aimed at ensuring that the clinical needs were covered by the available instruments, with minimal or no requirement for the use of instruments supplementary to those sets. However, the radical change in set design and use of much larger sets in groups observed in the Newcastle pilot study was not adopted at GOSH or UCLH.

A15 The new instrument sets were marked with the appropriate GS1 codes by the use of a 2D matrix technology to allow individual instrument identification. Each instrument code was registered to the tracking system, verified and then matched to the parent sets, but no grouping of the sets was used.

A16 The integrity of instruments within their work stream was tested by a number of dummy use/reprocessing cycles in which they were subject to tray and instrument level tracking. The results from these cycles were evaluated, with particular attention to set integrity and other aspects of patient safety, such as ensuring that the marking process had not compromised the instruments.

A17 The instruments were tracked at the point of receipt into the SSD and again prior to inspection before packing. Audit record-keeping files were ascribed to each set and the tracing system linked to patient age.

A18 NICE IPG 196 (2006) guidance and local policies applied within the pilot work call for additional restrictions on the use of these instruments. These restrictions exclude patients who have previously been operated on using non-age-restricted sets. In addition, the segregated instruments are not to be used on patients identified as being at risk, as defined by ACDP-TSE RM. Lastly, the instruments are not to be used on patients coming from overseas for treatment unless surgical and
other prion infection transmission risk factors can be demonstrated to be low as defined by ACDP-TSE risk definitions.

3. Keeping instruments moist between use and reprocessing

A19 The use of an environment designed to keep instruments moist after use and prior to reprocessing has been developed and evaluated using a single semi-commercial methodology. Although the pilot was restricted only to neurosurgery, staff reported that adapting the protocols for other surgical areas is achievable.

A20 The instruments are managed during use in a conventional way and no attempt is made to keep instruments artificially moist during the neurosurgical procedures; observation suggests that the instruments do not appear to dry out fully after use, except in the most prolonged surgical undertakings.

A21 After use, strategies to maintain the instruments in a moist atmosphere or environment were implemented: briefly, the instruments in their trays were inserted into a purpose-designed polythene bag and sprayed using a commercial product containing water, gel agents and a bacteriostat. The bag was then sealed with a commercial tie and removed from the theatre's dirty utility room in the usual way.

A22 The instrument trays remained in their bags until SSD staff were ready to commence the post-use checks and instrument tracking procedures. As the centres in this pilot used on-site reprocessing, the period between completion of a surgical procedure and the inspection in SSD was as short as one hour. However, for operational reasons, storage overnight or even over a weekend may be required.

A23 In conjunction with GOSH and UCLH, the sensitivity of the ninhydrin and biuret tests (see ‘Periodic tests’ in CFPP 01-01 Part D) for residual protein on instruments was evaluated under both laboratory and SSD conditions. The studies used residual protein measurements on both washed and visually contaminated stainless steel tags and performed by SSD personnel. The findings confirmed earlier results that both methods are comparatively insensitive at the detection of residual proteins on stainless steel.

A24 A new protein detection and quantification technology has been developed by Queen Mary University of London using OPA/NAC chemicals and a specifically binding isoindole fluorescent label. This involved spraying the instruments, allowing air-drying, and then viewing the fluorescence distribution on the instrument using a box (“G-box”) containing a light source, filters and a digital imaging system. The digital image output was mapped to a matrix display, and quantification software was used to generate greyscale or false-colour values to represent the strength of the fluorescent signal. Both the reagent and detection methods have been patented.

A25 Continuing uncertainties over toxicology related to the OPA/NAC chemicals and to the derivatives formed when bound to the detected proteins give rise to a need for caution at present. Whilst the existing evidence suggests there is very little risk to staff taking normal precautions when using the reagent or to patients from residuals on instruments, the work has nevertheless been conducted in parallel with the neurosurgical instrument stream rather than being applied to the instruments themselves. Tags (316-grade stainless steel) were used with a test soil prepared from rodent brain in order to simulate neurosurgical use and develop the approaches necessary to use the new system in an SSD. In addition, single-use neurosurgical instruments were also used in the pilot study.

A26 If an evaluation of toxicological acceptability is satisfactory, this methodology will be redeveloped for direct application to naturally contaminated instruments in use in paediatric neurosurgery.

Outcomes and benefits

1. Single-instrument and instrument set tracking

A27 Practical work on the pilot commenced with the installation and trial of instrument tracking systems in the SSD only. A single-instrument and tray-tracking methodology was developed, together with
a related audit procedure and controlled methods for repatriation of single instruments in the event of movement between or loss from sets. The pilot was then extended to include the installation of tracking equipment in the theatre, though this is restricted to instrument trays (and sets by inference). Conventional instrument accounting procedures are used to ensure patient safety and to confirm that all instruments are returned to the trays after use.

A28 The single-instrument tracking strategy used in the SSD was related to audit and record-keeping. The initial steps were carried out in the instrument assembly and packing (IAP) room and linked each individual instrument to the relevant tray. An alert system has been developed which indicates the absence of an instrument (which can have real importance in terms of the subsequent efficiency of clinical care), instruments included in the wrong tray and duplication of instruments within trays. The system ensured that trays exhibiting such defects were not released for use in theatre.

A29 Second-stage development covered the protocol and implementation for single-instrument tracking upon the return of instruments/trays to the SSD after use. The protocol required the identification of each individual instrument and repatriation of displaced instruments in the washroom as necessary.

A30 Further work has been conducted to optimise single-instrument scanning in the IAP room so that it may be carried out as a single exercise alongside the visual examination of each individual instrument.

A31 Patient tracing can only be linked to tray-level identification. For this, the GS1 coding structure was used, and the trace information enabled identification of the patient, with appropriate security barriers, and permitted the history of the tray to be seen, together with the names or codes for each of the operatives conducting the work. The computer system was developed to give near real-time operation so that look-back exercises to detect issues such as surgery to a vCJD at-risk patient are available as a rapid service, should they be needed.

A32 GOSH is contemplating a move to off-site SSD services and has accordingly conducted an evaluation of single-instrument scanning post-surgery, using space made available in the dirty utility rooms. To date, this approach works well and observations suggest that instrument washing prior to code scanning is unlikely to be routinely necessary.

2. New instrument sets for patients born after 1 January 1997

A33 The previously mentioned desktop exercise defined the working rules for this part of the pilot, as described in ‘Methods and approaches’ above. Clinical use of the new instrument sets is now in progress, governed by strict protocols derived from the NICE IPG 196 guidance in terms of determining which patients are selected for the use of the post 1 January 1997 instrument stream, as described above. Little or no leakage of instruments between this second paediatric stream and the body of paediatric instruments has been observed. Additionally, the protocols governing instrument tracking, traceability and the relationship to those categorised patients work well and permit the history of instrument use to be accurately plotted.

3. Keeping instruments moist between use and reprocessing

A34 The advantages of this procedure in terms of aiding the effectiveness of subsequent decontamination, particularly in respect of protein contamination removal, are recorded in (4) below. It is intended that post-surgery moist instrument environment, protein quantification and washer-disinfector optimisation will be considered together for the remainder of the pilot.

A35 In operational terms, the additional procedures in theatre were limited to the placing of trays – following normal audit to ensure that all instruments are present – into specially designed and robust plastic bags. This process was removed to the dirty utility room where space was allocated for the purpose. The process was very simple, involving only the bagging described here, followed by the use of a spray/ gel and closure of the bag with a purpose-made tie. Bag failure and/or the loss of tie have not been observed. The procedure was conducted by a designated trained member of theatre staff and adds only some three-to-five minutes to the normal recovery and removal of surgical instruments following closure of a neurosurgical procedure.

A36 For some instruments, exposure to this moist environment appears to have produced a marginal increase in the rate of polished surface deterioration. This effect was variable across
instrument sets, with very little surface quality loss being apparent in the higher grade stainless steel instruments, whilst some instruments thought to have been constructed from lower grade steel exhibited noticeable deterioration.

A37 Teams contemplating the modernisation of instrument sets as part of a drive towards more efficient surgery would be well-advised to consider ensuring that any new instruments purchased have a high corrosion resistance so as to better support a move towards the use of moist conditions.

4. Protein detection and quantification technology

A38 In the trials using stainless steel tags, a five-order reduction in the total mass of residual protein contamination following processing of moist instruments through a standard cycle incorporating the use of a proteolytic enzyme-based detergent was observed compared to dry instruments processed without the proteolytic agent. This effect has been observed over a large number of repetitions of the pilot exercise, though the contribution made by the components within the process cannot be resolved. In addition, if there was a difference caused by the detergent, it is not known whether it was a difference in the surfactant component or if it was due to a proteolytic component of one of the detergents.

A39 Since the ninhydrin and biuret tests were confirmed to be relatively insensitive in detection of proteins on instruments, a much improved procedure is required. The procedure should be relatively cheap and easy to use in a SSD environment but most importantly it should be sensitive towards protein residues on instruments.

A40 The OPA/NAC fluorescence and digital camera-based system has proved effective in terms of both the detection and a degree of quantification of protein residues on washed and disinfected items. However, safety issues identified in the pilots remain unresolved, and so a methodology employing stainless steel tags contaminated by rodent brain homogenate was used.

A41 First among the concerns is the toxicology of the OPA/NAC fluorescent agent. This is being investigated but until the local ethics group are satisfied that the materials are non-toxic or do not make contact with the patient, the envisaged testing of surgical instruments in actual use cannot be pursued.

A42 If and when the process is established to be acceptable, work will move to direct assessment of contamination levels on instruments kept moist following neurosurgical applications.

A43 A number of key issues have emerged and are under current consideration: Current pilot information suggests that the most appropriate strategy for protein testing will involve conducting the OPA/NAC fluorescence examination during inspection following washing and disinfection. To remove the chemistries used and any derived products, a repetition of the washing and disinfection cycle for the whole set – regardless of the test status of individual instruments contained therein – will be necessary.

A44 See the section on ‘Periodic tests’ in Chapter 2 of CFPP 01-01 Part D.

Revision of instrument set: design and management

A45 Centre involved: Newcastle upon Tyne Teaching Hospitals NHS Trust.

Aims and objectives

A46 This pilot was established to investigate methods of reducing the risk of CJD transmission between a carrier patient and subsequent patients subject to surgical treatment using the same reprocessed instruments. This accords with the principles of NICE IPG 196 (2006).

A47 In practical terms, two requirements were examined:

a. the prevention of migration of surgical instruments from one neurosurgical set to another; and

b. enabling the control of instrument-specific risks by the use of single-instrument tracking via GS1 unique identifiers and a barcode system.

A48 Neurosurgical and posterior ophthalmic (PO) procedures were selected as the area for pilot activity because of the potentially high risk of CJD transmission via surgery on these tissues.

Method and approach

A49 The jointly agreed methodology between DH, the Advisory Committee on Decontamination Science and Technology (ACDST), and Newcastle upon Tyne Teaching Hospitals NHS Trust was originally based on the repatriation of instruments to their
sets by the use of records and audit. This required data collection from individually marked instruments, which during initial trials proved cumbersome and demonstrated that routine leakage between sets in both the operating and decontamination environments ran at potentially significant levels.

### A50
The pilot team took the view that the high levels of leakage observed and the difficulties in tracking supplementary instruments warranted fundamental review of the goals of the pilot; the appropriateness of the set structures and contents for use in modern neurosurgery was questioned.

### A51
The pilot direction was therefore changed to focus upon the appropriateness of the neurosurgical sets used in Newcastle to the range of techniques to which they are applied.

### A52
A specific review of neurosurgical sets for a range of major interventions was conducted by a team consisting of decontamination specialists, surgeons, nurses and theatre technical staff. This showed poor correlation between the operative procedure design and the instruments provided to support the conduct of that procedure, with very high numbers of supplementary instruments routinely being used (Table A1). The set structures and contents were reappraised and new, larger sets (commonly referred to as “big sets”) were created. In many cases, unused instruments were removed from sets, and frequently used supplementaries were added to the sets with which they were being used. This process was typified by the amalgamation of existing instrument sets (for example “craniotomy light” and “craniotomy heavy”) into one casket/instrument set group.

### A53
This work led to a smaller number of larger sets within the neurosurgical area and a very marked reduction both in the use of supplementary instruments and in leakage between sets. This is a product of the reduced probability factors that arise from the sets being both larger and more appropriate to their application.

### A54
In order to ensure that sets used for procedures where a high risk of CJD transmission may occur should a carrier of the disease be encountered (that is, work on the central nervous system (brain) or PO structures), a colour-coding system was introduced. These colour codes differentiate sets and their associated caskets according to the CJD transmission risk group into which the associated surgical procedures fall.

### A55
This rationalisation was backed by continued use of GS1-based set tracking and the selective application of single-instrument tracking techniques.

### A56
In addition to NICE recommendations that leakage of instruments used for high-risk tissue surgery should be minimised, NICE has also recommended that sets used on patients born after 1 January 1997 be kept completely separate from those used for older patients. As a safeguard, Newcastle introduced colour-coded lids for these differently designated sets. The sets for adults and older children are blue, whilst yellow lids are used for the younger age group. This simple technique has proven reliable in practice and imposes very low operational overheads.

### A57
These techniques are complemented by an audit based on written procedures, carried out both by technicians in SSDs and in a near-identical way by those overseeing the use of instruments in the operating theatres. This step is designed to ensure that sets remain complete and that any residual leakage is detected. In addition, the audit process supports the detection of unsatisfactory instruments that may compromise surgical quality. It has also performed well in exposing the absence of instruments from sets, which may also have clinical consequences.

### A58
The tray tracking system reconciles the trays with their parents sets and with the casket system, where employed. At the set level, the unique identifiers permit tracing to each patient with whom the instrumentation is used, via a link to the patient administration systems.

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### Table A1
Numbers of trays and supplementary instruments used in four Newcastle hospitals between April 2006 and March 2007

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Number of trays</th>
<th>Number of supplementary instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal Victoria Infirmary (RVI)</td>
<td>106,991</td>
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<tr>
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<tr>
<td>Newcastle Dental Hospital (NDH)</td>
<td>154,068</td>
<td>167,351</td>
</tr>
</tbody>
</table>
Appendix A: Reports from DH pilot studies concerning the implementation of NICE IPG 196 (2006) guidance

A59 The success of the audit technique is critically dependent on staff training and on the maintenance of instrument lists so that these keep pace with both the development of surgical techniques and the actual inventory present.

A60 The audit and record-keeping approach is supplemented by the printing of barcoded records, which are entered into the patient’s notes. This is a safeguard against the risk that a failure in computer-based record-keeping might compromise the track-and-trace capability of the local service.

Outcomes and benefits

A61 The participating Trust has recognised the following marked benefits:

a. Standards of accountability and audit performance in terms of supporting surgery through provision of appropriate quality-controlled surgical instruments exhibit marked improvement.

b. The new system is shown to be sufficiently robust that sets may be tracked throughout the entire use and decontamination cycle with no detectable loss of content stability. The tracking techniques are applied prior to instrument washing, prior to packing of instruments for subsequent sterilization and upon unwrapping in the operating theatre.

c. Audit has shown that the system permits very reliable linkage between the patient, procedure and the instruments used within the overall record.

d. Linking the comprehensive record system to engineering quality system records and operator identification gives a comprehensive overview and supports effective fault-finding when required.

e. Operational separation of high-risk tissue instruments from other sets has been achieved without apparent error.

f. Operational separation of those sets used with children born after 1 January 1997 has proved fully effective in the protection of those children against the use of uncontrolled instruments in neurosurgery.

g. The use of supplementary instruments in neuro- and PO surgery and even in other surgical areas has been markedly reduced and where use of supplementary instruments is necessary, it can be identified through use of the record-keeping system.

Pilot conclusions

A62 Large surgical care providers are confronted with substantial problems in ensuring instrument set stability and the minimisation of supplementary instrument use, partly owing to their high throughput of patients, both generally and in the high-risk tissue-related services. Inappropriate or outdated set design is shown to add significant challenges to those inherent in large-scale instrument management.

A63 The redesign of instrument sets to better match clinical need and the simplification of the clinical procedure categorisation techniques applied gives rise to larger sets but these are very much more easily managed and exhibit much improved stability in terms of instrument retention.

A64 The use of simple colour-coding techniques to differentiate between high-risk instrument sets and those in general use has proven viable and offers near-complete insulation against movement of instruments between the high- and other risk category work. Similarly, colour-coding has demonstrated a high level of reliability in ensuring that those sets used with younger patients are well-protected from inadvertent use with the older cohort. However, the NICE criteria for the post 1 January 1997 group include other factors such as whether the patient has been subject to previous neurosurgery or (applying ACDP-TSE guidance) has had a large number of blood transfusions. Therefore scope for error in the classification of a child remains.

Single-instrument tracking and management using a commercial decontamination service provider

A65 Centre involved: Birmingham Children’s Hospital NHS Trust.

Aims and objectives

A66 This pilot was designed to investigate practical issues surrounding the implementation of NICE IPG 196 (2006) guidance, but in the context of a commercial contract for the external supply of decontamination services as opposed to the internal SSD arrangement at GOSH/UCHL and Newcastle upon Tyne Teaching Hospitals NHS Trust.
Birmingham Children’s Hospital (BCH) is part of the pan-Birmingham Group that comprises eight hospitals, all of which employ a decontamination services provider under contract.

The specific objectives of the pilot are:

a. Limitation of instrument migration between sets via implementation of single-instrument tracking for neurosurgical instruments throughout the use/decontamination cycle.

b. Instrument set separation for patients born before and after 1 January 1997 and CJD at-risk patient identification protocols for use with this group.

BCH offers advanced neurosurgery and posterior ophthalmic work, but exclusively employs single-use instruments for the latter, so the scope of the pilot in terms of reusable instruments is limited to neurosurgery instruments.

Method and approach

Supplementary instruments are regularly used at BCH and the other trusts in the pan-Birmingham Group. This may in part be due to the decontamination pricing structure in effect at the decontamination services provider, which is organised in bands based on how many instruments are in a tray. Decontamination staff have observed that trays tend to be filled to the maximum number possible within a given pricing band and further supplementary instruments used as necessary, as these are relatively inexpensive to have decontaminated.

In the current arrangement, instruments are tracked at tray level at several stages throughout the transport, initial inspection, washing/disinfection and sterilization cycle, then again onto outbound transport and at least on arrival at, and collection from, stores at BCH. There are facilities to allow more detailed tracking within BCH but these are not presently being exploited.

Trays of instruments are assigned GS1 codes by the decontamination services provider and these persist throughout the lifetime of the tray. These codes are linked to records detailing the contents of the tray. Supplementary instruments are also assigned GS1 codes that describe the type of instrument but these codes are not permanent and are reassigned after the instruments are returned for reprocessing. Each item, whether a complete tray or a supplementary instrument in a peel-pouch, has a label that includes two peel-off 2D data matrix stickers, carrying the GS1 code, which are used by BCH to manually attach to the decontamination services provider’s receipts and to the patient’s notes. This paper-based system provides the only traceability to the patient in the pre-single-instrument tracking phase.

Loan instrument sets are tracked in the same way, but they present additional challenges to maintaining set stability as anecdotal evidence suggests that loan instruments may be further borrowed and possibly used at other sites whilst on loan to a specific trust. Instruments missing from any set are noted on the labels printed by the decontamination services provider, which also sends notification emails to BCH each time set contents are checked during reprocessing. At BCH, the decision is made whether to proceed with the use of the set without the instrument(s) or to quarantine the set until the missing instruments are found and repatriated to it, a process that is managed manually.

In preparation for the implementation of single-instrument tracking, BCH and its decontamination services provider spent a considerable period evaluating instrument marking options, as it was essential that the marking should not interfere with either use or reprocessing of the instruments. The solution chosen was to laser-etch a 2D matrix code onto each instrument, a system that is flexible in the range of instrument sizes that can be accommodated, with readable codes down to 1.1 mm. Initial trials have shown that these codes are not always easy to scan. Moreover, these etched patterns wear off over time, especially on smaller instruments, lasting typically a matter of months.

An upgrade of the tracking software used by both the trust and the provider was also necessary to add support for single-instrument tracking. The decontamination services provider has also had to address staffing issues relating to the additional workload that scanning each individual neurosurgical instrument will entail, and logistical challenges in respect of integrating a single-instrument tracking stream within its existing tray-level tracking workflow.

Separation of instrument sets for the patient groups born before and after 1 January 1997 involved the purchase and laser-etching of four new sets of neurosurgical instruments for use on the latter group. These new sets are further identified by the
Appendix A: Reports from DH pilot studies concerning the implementation of NICE IPG 196 (2006) guidance

A77 The identification of CJD at-risk patients to ensure appropriate usage of the new neurosurgical instrument sets has resulted in the development of a checklist that hospital staff can complete using information determined during routine clerking. A CJD-specific questionnaire had been under development but was abandoned as BCH’s governance services were concerned that it would cause unnecessary anxiety and would be difficult to administer to the hospital’s patient population, many of whom do not have English as a first language.

A78 If a patient born after 1 January 1997 requires a high-risk procedure, the new neurosurgical instruments are used, provided that the patient has not already undergone surgery with an older set of instruments at BCH or at another hospital where the CJD risk status of the instruments used is unknown. Patients who have received multiple blood products and are in the “at increased risk for public health purposes” category, such as haemophiliacs, are excluded from use of the new neurosurgical instrument sets, though BCH has been able to confirm that Octaplas, a blood plasma product prepared from pooled blood donations, does not count towards patients’ transfusion histories. A consideration by BCH of types of neurosurgery patient suggests that very few neuro-oncology patients receive large amounts of blood products and then require further neurosurgery: a maximum of one per year.

A79 It is also possible that severe trauma cases could also require high-risk surgery after receiving large quantities of blood products but this would be a very rare event indeed.

Outcomes and benefits

A80 The single-instrument tracking went into effect from 1 January 2012. This date was chosen as an easily remembered point for both BCH and decontamination provider staff to switch to the new procedures.

A81 The identification of the new sets of neurosurgical instruments for the post 1 January 1997 cohort is in place and working well. Although this measure cannot reveal whether an instrument has migrated between post 1 January 1997 sets, it does prevent undetected mixing of high- and low-risk sets, in accordance with NICE IPG 196 guidance. As a children’s hospital treating patients of up to 18 years of age and generally not admitting new patients of more than 16 years, BCH will soon reach the point where its entire patient population will be in the post 1 January 1997 group, though there will continue to be issues regarding patients previously treated with older instruments or at other hospitals.

A82 BCH anticipates having to maintain separate instrument pools for a further 15–20 years, although a progressively larger proportion of patients will be treated with the new instrument sets.

Pilot conclusions

A83 Simple instrument colour-coding akin to the scheme adopted in Newcastle (see link below) appears to be a robust solution for maintaining separate pools of instruments for sectors of the population born before and after 1 January 1997, and should provide strong CJD protection for the younger cohort, provided that patient CJD risk categorisation is carried out correctly. The system has to be designed to err on the side of caution and thus may exclude CJD-free patients from access to the new instruments because they have previously had high-risk procedures performed at BCH or elsewhere with instruments whose risk status is unknown. It is possible that over time as this aspect of NICE IPG 196 guidance is more widely adopted and recorded, more repeat patients could be given access to the new instruments.

A84 What this system alone cannot do is detect or prevent instrument migration between sets within the pre or post 1 January 1997 groups, or provide traceability to the patient beyond the manual sticker-based approach described above. It is anticipated that the introduction of single-instrument tracking in 2012 will address these aspects of NICE IPG 196 guidance. A reappraisal of set redesign to reduce or ideally eliminate the use of supplementary instruments as carried out in Newcastle (see paragraph A45) would require a joint process between BCH and its decontamination services provider that would almost certainly have implications for the latter’s
business with other trusts within the pan-
Birmingham group.

Protein quantification using
epifluorescence scanning

A85 Centres involved: University of Edinburgh/Royal
Infirmary of Edinburgh.

A86 The in situ protein-detection techniques developed
by Dr Helen Baxter, Dr Anita Jones and Professor
Robert Baxter at the University of Edinburgh were
established out of research into the efficacy of
radio-frequency low-pressure gas-plasma cleaning
and decontamination methods. These methods are
capable of removing residual contamination on
instruments to a level where no organic residues
can be detected by scanning electron microscope
(SEM), so a more sensitive detection technique was
required. This led to the development of an
epifluorescence-based scanning technique that is
now being used to assess protein contamination
levels on reprocessed surgical instruments supplied
by the Royal Infirmary of Edinburgh.

Aims and objectives

A87 The aim of the pilot was to establish and validate a
means of quantifying residual contamination on
reprocessed instruments that was sufficiently
accurate, practical and robust for use in an SSD to
reduce risk of transmission of prions via surgical
instruments.

A88 The three objectives within this were to:

a. determine a statistically valid average value for
residual contamination on instruments
reprocessed using current washing–disinfection
processes that were considered fit for reuse
under current testing regimes;

b. determine an acceptable threshold value for a
clean instrument in terms of the new protein
detection and quantification technique;

c. develop/reconfigure the detection device
software to yield a “traffic light”.

Method and approach

A89 The underlying principle for protein detection in
this pilot was the excitation and subsequent
detection of fluorescence of proteins labelled
through reaction with fluorescein isothiocyanate
(FITC). Test discs of stainless steel and surgical
instruments to be scanned were immersed in a
solution of FITC for five minutes, rinsed in water
to remove excess reagent and allowed to dry.

A90 The Epifluorescent Surface Scanner (EFSCAN) was
built in partnership with Edinburgh Biosciences
Ltd and comprised a scanning bed over which an
optical fibre scanning head linked to a
photomultiplier tube was moved under computer
control to build up (pixel-by-pixel) a 2D image of
the scanning area. This process takes approximately
14 minutes at the higher of two available resolution
settings. Software captures and processes the
fluorescent intensity data from each scan site,
equivalent to an area of 0.5 mm². Initial tests were
conducted using stainless steel tokens inoculated
with bovine serum albumin (BSA) before moving
onto a selection of 42 instruments at the end of
their usable life donated by the Royal Infirmary of
Edinburgh.

Outcomes and benefits

A91 Processing of the 2D fluorescence intensity data
enabled 3D plots to be made to visualise the
distribution of protein contamination and
locating hot spots of unusually high contamination
and relating them to features of the scanned
instrument’s structure. Calibration of the system
enabled protein concentration-per-pixel to be
established. Further calculations converted these
values into absolute protein concentrations,
typically in the ng/mm² range, which were then
used to calculate total and averaged protein levels
over the scanned parts of the instrument. Work has
been done to relate these measured values to
washer-disinfector validation tests based on visual
assessment in order to help define a scale for
measurement optimisation.

A92 There are continuing deliberations over how the
data should be used to assess instrument cleanliness
in terms of total load, averaged or “hot spot” values
and how these relate to a broad initial aim of
producing a hundredfold improvement over visual
methods. Progress has been made towards defining
thresholds for a traffic-light system, in which initial
values of less than 1.5 ng/mm² averaged over the
scanned surface rates a “green” (suitable for use),
more than this value a “red” (not suitable for use,
process and test again) and any individual hot spot
in excess of 10 ng/mm² found in an otherwise
“green” scan will trigger an “amber” alert. Applying
these threshold values to a sample of 42 reprocessed
instruments from the Royal Infirmary of
Edinburgh SSD produced a 93% pass rate, though
seven instruments had hot spots, four of them in the group that passed on average protein concentration levels.

Pilot conclusions

A93 The EFSCAN project has shown that this technique can locate and quantify protein contamination on instruments down to very low levels via a process that is relatively simple to set up and operate. Optimisation for a specified measurement range is a logical next step but work remains to be done in defining what the target range should be. Measurements and statistical analysis of a larger sample of surgical instruments from the Royal Infirmary of Edinburgh SSD should help establish this.

A94 As with the Graet Ormond Street Hospital (GOSH) and Southampton pilots, an investigation into toxicology is required before scanned instruments can be returned to the Royal Infirmary for reuse. While fluorescein is considered safe and indeed used in some surgical procedures, it is necessary to investigate the possible effects of derivatives. It is not anticipated that this will raise any significant issues as the quantities of protein are at worst in the submicrogram range, virtually all of which is removed by subsequent washing.

A95 Significant improvements in the speed of the EFSCAN scanning unit could potentially be made if the design were to be developed for commercialisation.

A96 Current issues being addressed are the software interface design and measurement techniques, in terms of how much data would be presented to the SSD user, particularly in the case of an “amber” result and whether the lower-resolution (and therefore faster) scanning mode would be able to detect hot spots. Linking scanned instrument data to GS1 coding for single-instrument tracking should be a relatively straightforward exercise and would enable a variety of data, from simple pass/caution/fail verdicts to complete fluorescent image capture, to be associated with the instrument for record-keeping and audit purposes.

Protein quantification using EDIC/epifluorescence microscopy

A97 Centres involved: University of Southampton, University Hospital Southampton and Southampton General Hospital.

A98 The pilot work at Southampton is based on a technique called EDIC microscopy, originally developed for detection and inspection of biofilms and bacteria on surfaces. The University team, led by Professor Bill Keevil, has been carrying out a project funded by DH to develop a protocol for the detection of protein using this technique.

Aims and objectives

A99 As with the other protein detection pilots (GOSH/Queen Mary University of London, and Edinburgh University), the specific objectives included:

a. To determine the effectiveness of the technique in question both in terms of locating and of quantifying residual protein on reprocessed surgical instruments.

b. To assess the operational impact of the potential adoption of the new technology in terms of SSD practice and subsequent use of instruments sampled from the SSD.

c. To provide guidance recommendations for the use of the new methods.

d. To generate information on capital, implementation and operation costs.

Method and approach

A100 As the EDIC microscopy had already proven to be a powerful tool for biofilm and bacteria-related work, the requirement was to find a suitable labelling technique that would provide sufficient sensitivity and specificity for protein detection.

A101 Sypro Ruby, a highly-sensitive fluorescent stain, was selected as it is capable of revealing proteins in sub-nanogram quantities per mm² and, through use of a thiazole marker (which causes light of a different wavelength to be emitted), is also able to detect plaque proteins, particularly relevant because vCJD forms this type of protein. With no direct test for prions yet available, detecting prion-associated amyloid is one step more specific than a generic protein test.

A102 In the context of testing for protein residues on reprocessed surgical instruments, the ability to test directly for the more hydrophobic proteins, which may be expected to be more resistant to removal in the washer-disinfector process, is additionally valuable as a tool in testing the efficacy of various types of cleaning process.
The EDIC/epifluorescence (EDIC/EF) technique was used in conjunction with a digital camera to enable the capture of photomicrographs, firstly of 316-grade stainless steel coupons that had been dosed with varying amounts of mouse-brain homogenate. From these, the threshold of detection was established via a panel of eight independent observers. Inspection at multiple points of a variety of surgical instruments that had been through standard washer-disinfector cycles enabled a contamination index (CI) to be constructed, ranging in numerical score from 1 (no detectable protein contamination) to 4 (gross contamination). These values have been correlated against observed particulate height and width to yield corresponding protein concentrations, ranging from 0–42 ng/mm² for a CI of 1 to >4.2 µg/mm² for a CI of 4.

A variety of further experiments involving the use of the EDIC/EF technique has subsequently been carried out. These include:

- quantification of the sensitivity of established protein detection with ninhydrin and biuret tests;
- residual protein measurement on 260 surgical instruments;
- measurement of bioburden on diathermy instruments;
- a demonstration of amyloid-specific detection at attomole levels;
- a comparison of visual assessment of instrument cleanliness and protein contamination as measured using EDIC/EF microscopy;
- a comparison of protein contamination of reprocessed instruments when handled by operators wearing gloves against handling with bare hands; and
- a comparison of the cleaning efficacies of a number of commercial cleaning chemistries currently used in washer-disinfectors.

Investigations into the effect of drying time, maintenance of a moist environment and/or the use of pre-soak treatments on washer-disinfector cleaning efficacy have also been made and the results published.

**Outcomes and benefits**

The published work from this pilot shows that the EDIC/EF technique for in situ protein detection is both rapid and sensitive, particularly compared to established swab-based protein detection methods. The microscope operates at a relatively large distance from the subject (compared to other microscopy applications), it is possible to work with the irregular shapes and contours or real surgical instruments without the need for oil or cover slips.

The various experiments described above have yielded a wide range of findings. In brief they include:

- The EDIC/EF technique with Sypro Ruby stain enables detection of residual proteins in concentrations between approximately 85 and 175 pg/mm² (at minimum level of detection (MLD) of 50 and 75 respectively).
- The minimum detection levels for ninhydrin and biuret tests were found to be 9.25 and 6.7 µg (respectively, both at MLD75), while visual assessment of contamination, although found to correlate well with measured levels for simple instruments, was prone to severely underestimating contamination in more complex ones.
- A study of 260 surgical instruments that had been reprocessed and were deemed clean showed that over 60% had a protein soiling level of between 0.4 and 4.2 µg/mm². This study also found non-protein crystalline deposits on the instruments. These may originate from washer-disinfector chemistry and it appears that they act as preferential attachment sites for protein residues; the toxicology of the deposits is as yet unknown.
- Instrument handling by cleanroom staff without gloves showed a five-to tenfold increase in protein present on reprocessed surgical instruments compared with those handled by staff wearing gloves, although protein added this way is unlikely to pose a risk to patient health;
- The comparison of cleaning chemistries showed that all the tested products were only partially effective under the manufacturers' recommended conditions, with a considerable variation in efficacy between products. Brain homogenates from mice infected with the ME7 strain of scrapie were used for testing on stainless steel tokens and it was observed that PrPSc (scrapie prion protein) constituted the bulk of residual protein after passing the
Appendix A: Reports from DH pilot studies concerning the implementation of NICE IPG 196 (2006) guides

contaminated tokens through the recommended washer-disinfector cycles; neurosurgical instruments stained for comparison with the tokens were found to harbour amyloid and general protein contamination.

**Pilot conclusions**

A108 The pilot study has shown that EDIC/EF microscopy is a sensitive and versatile measurement technique, able to detect and quantify plaque proteins of the type associated with vCJD in addition to more general protein contamination. Through use of visible light techniques, additional types of contamination on reprocessed instruments and the interaction between these and protein residues may be observed, enabling a more complete picture of instrument condition to be gained.

A109 Further work at the SSD at Southampton General Hospital is being carried out to evaluate current processes across several different washer-disinfector models and cleaning chemistries, both in absolute terms and comparing to ninhydrin/biuret testing. A suitably equipped microscope had been installed and staff were being trained in its operation; protocols for instrument testing were being developed and the toxicology of Sypro Ruby will be further investigated as part of this process, though it is thought to be non-toxic at any concentration likely to be encountered in this application. Lab-based experimentation with a lower-power lens is also taking place to establish limits of detection with a wider field of view.
B1 This report describes the aims, methodology, findings and recommendations from a survey of surgical instrument decontamination in 30 selected NHS and private healthcare providers and their associated decontamination facilities in England where neuro- and posterior ophthalmic (PO) surgery are carried out. It also briefly describes related work based on the findings of the survey that was carried out from late 2008 to December 2010 at three sites chosen to pilot improvements in risk control related to surgical instrument management and decontamination (Appendix A contains the finalised reports from the pilot studies).

B2 The survey was designed to investigate the extent to which risk-reduction measures aimed at minimising the possibility of prion transmission via surgery involving high risk (in vCJD infectivity terms) tissues have been applied. Specific reference is made to the implementation of guidance contained within the NICE IPG 196 (2006), which deals with instrument management in pursuit of risk reduction via the retention of instruments within stable neurosurgical and PO sets. NICE IPG 196 (2006) also recommends that separate and identifiable instrument sets for patients born before and after 1 January 1997 are provided and rigorously maintained. Further advice from the Advisory Committee on Decontamination Science and Technology (ACDSP-TSE RM has published an extensive series of guidance documents aimed at risk control in connection with prion transmission, some of which concern surgical or other interventional procedures. The implementation of this guidance has been incorporated investigated closely in this survey.

B3 ACDP-TSE RM has published an extensive series of guidance documents aimed at risk control in connection with prion transmission, some of which concern surgical or other interventional procedures. The implementation of this guidance has been incorporated investigated closely in this survey.

B4 The initial field survey was carried out in mid-2008 and involved joint research teams comprising DH representatives and local staff gathering information via a detailed questionnaire. The results were analysed using a figure-of-merit approach to weight the response data relating to the various measures under investigation according to their importance and effectiveness in reducing the risk of prion transmission.

B5 The principal findings are that while the EN/ISO/BS decontamination standards are found to be satisfactorily applied, the implementation of NICE IPG 196 (2006) was relatively inconsistent, particularly in respect of adopting separate surgical instrument sets and streams for use with children born after 1 January 1997. Specifically, very few centres have simultaneously combined the requirements for new instrument sets for this age group with instrument tracking and adequate protection against instrument leakage. Further, no centre, outside the pilots, has achieved the full NICE IPG 196 risk reduction benefit intended.

B6 The implementation of ACDP-TSE RM guidance was also inconsistent, though two-thirds of centres achieved a high standard of compliance such as to generate a reasonable contribution to risk control.

B7 Another area of concern is a lack of testing of both electrical safety and calibration, especially with regard to diathermy equipment. Although not specifically related to prion transmission risk reduction strategy, this is an area that requires urgent attention.

B8 The findings of this survey and subsequent development work at the pilot sites form a substantial part of the evidence base for the guidance now provided in CFPP 01-01. Combining the survey findings with the subsequent guidance implementation pilot work makes it possible to deliver a more coherent policy and guidance package.

The National Decontamination Survey can be accessed via this link.
Appendix C: A patient and public perspective

C1 This guidance has been written for care commissioners, care providers and care quality regulators to improve standards in the decontamination of surgical instruments and to ensure that Essential Quality Requirements are met by every hospital and medical facility conducting surgery in England, and that healthcare organisations have a plan in place to move towards Best Practice, where possible, according to the needs of the patients that they deal with.

Why the need for the guidance?

C2 Most people who go to hospital for a surgical procedure have a good experience and outcome. However, in some instances, the experience and outcome may not be as expected for a number of reasons. Those reasons involving surgical instruments include:

- The instruments may not have been sterilized adequately, meaning that the patient may have been exposed to infectious microorganisms and may develop an infection as a result.
- Some people may have been operated on using instruments that, subsequently, are found to have been used on a patient who has developed CJD (an infectious neuro-degenerative disease) or a related disease. These patients must be identified and informed of the risk of infection and developing CJD in the future.
- Key surgical instruments required for a procedure may be missing from the instrument set. This usually results in operations being cancelled at short notice with great inconvenience to the patient.
- Instruments may be dropped during surgery, meaning that surgical procedures may need to be stopped or delayed before they have been finished.
- Patients who have been told they are “at risk” of developing CJD, through exposure to the infectious agent either from contaminated instruments or through contaminated blood products, may find that the surgical procedures they need are cancelled or postponed while a risk assessment is made and provisions to isolate the instruments following the surgery are made.

C3 The guidance is intended to improve patient outcomes by requiring that systems are put into place to reduce infection, to ensure risk assessments are undertaken for all areas of the sterilization/decontamination process and to ensure that instruments remain in their sets by tracking them at all times.

How does this affect me?

C4 As a patient who may need a surgical procedure, or as a carer for someone who may need surgery, it is important that you get the best treatment possible and that you feel that everything is being done to safeguard your well-being.

Am I at risk of CJD infection from surgical instruments?

C5 The infectious agent that causes CJD and related diseases is made of protein and is very difficult to destroy. It clings to the surface of instruments and most hospital sterilizers cannot guarantee that they have removed all the protein from the surface of instruments and destroyed the agent. If people who already have CJD and are not aware of it have surgery, they could potentially infect the instruments used during the surgery and this infection can then potentially be passed on to other people. Steps are being taken to develop new technologies and better sterilization techniques to remove and destroy the agent, and this guidance covers the adoption of such technology as it becomes available. This aims to make surgery as safe as possible for the patient.
What is being done to improve patient safety?

C6 The guidance implements a number of quality standards and guidelines from regulatory and learned bodies to ensure that:

- surgical instruments are coded and tracked and remain within their instrument set;
- surgical instruments can be traced back to the patients they have been used on;
- extra instruments required for a particular procedure are used only once or kept within the set for that procedure;
- a separate pool of instruments is kept for children born after 1 January 1997 to make sure that they are not exposed to the CJD agent;
- sterilization procedures and facilities within the hospital are fit-for-purpose and meet Essential Quality Requirements;
- where high-risk surgical procedures are required (for example, neurosurgery or post-ophthalmic surgery), appropriate risk assessment is carried out and reflected in the local policies;
- the method used for sterilization is suitable to the instrument and will not damage the instrument;
- hospitals carry out risk assessments wherever possible to prevent failures in the decontamination procedures.
Appendix D: Standards relevant to decontamination

Standards relevant to decontamination processes and equipment


BS EN ISO 17665-1. Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices. (This includes porous load and fluid sterilizers (except where used for medicinal products), and sterilizers for unwrapped instruments and utensils.)


BS EN 13060. Small steam sterilizers.


BS EN ISO 15883-1. Washer-disinfectors. General requirements, terms and definitions and tests.

BS EN ISO 15883-2. Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.


Standards relevant to decontamination management


Standards relevant to safety requirements for decontamination equipment

BS EN 61010-2-040. Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.


Standards relevant to medical devices

BS EN 556-1. Sterilization of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for terminally sterilized medical devices.

BS EN 556-2. Sterilization of medical devices. Requirements for medical devices to be designated ‘STERILE’. Requirements for aseptically processed medical devices.

BS EN 1041. Information supplied by the manufacturer of medical devices.

BS EN ISO 17664. Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.

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A survey of instrument management and decontamination in high-risk tissue surgery centres
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Executive summary

Introduction

The principal purpose of the National Decontamination Survey (NDS) 2008–10 was to determine the progress made by neuro- and posterior ophthalmic surgical healthcare providers and decontamination service providers in implementing:

- National Institute of Clinical Excellence (NICE) IPG 196 (2006) ‘Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures’ prion transmission risk reduction guidance; and

- Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Risk Management subgroup (ACDP-TSE RM) guidance on specific risk control related to patients at risk of CJD and variant CJD (vCJD). This includes TSE Infection Control Guidance Annex J, which is concerned with patients who are to have neuroendoscopy or surgery on tissues considered high risk in terms of potential prion transmission.

In addition, the survey aimed to assess compliance with decontamination quality systems and engineering standards described in Health Technical Memorandum (HTM) 2010 – ‘Sterilization’ and HTM 2030 – ‘Washer-disinfectors’.

The survey was designed to assist in refining the risk estimates related to potential further spread of human prions via surgical instruments. To this end, the survey results were processed using a figure-of-merit (FOM) method, which is designed to recognise progress and to highlight risk-related failings and omissions.

The key questions used to interpret the survey data were developed with advice from the Engineering and Science Advisory Committee into the decontamination of surgical instruments including prion removal (ESAC-Pr) (subsequently the Advisory Committee on Decontamination Science and Technology (ACDST) prior to its disbanding at the end of 2010) and ACDP-TSE RM committee chairs, supported by appropriate learned and professional bodies.

The survey covered 30 centres offering neurosurgical and/or invasive posterior ophthalmic procedures, including both NHS and private providers. These were se-
lected by reference to the appropriate learned and professional bodies, with a view to capturing a large proportion of those carrying out invasive procedures on tissues considered to be high-risk in prion transmission terms, specifically the brain (subdural), retina and optic nerve. These tissues can carry a level of infectivity such that if surgery is conducted on a patient who is an unsuspected carrier of vCJD or other prion disease, the risk of onward transmission via the instruments used on that patient is significantly greater than for surgery involving other anatomical areas. For this reason, the survey does not offer an overview of general acute unit surgical instrument decontamination as a whole, and should not be regarded as such.

Note:
The term “centre” is used throughout this report. In most cases, it refers to a single site upon which both neurosurgery and/or posterior ophthalmic work is performed and the decontamination of the instruments used is also conducted. However, in some instances, a centre may conduct the surgery with the decontamination being performed elsewhere.

The fieldwork for the survey was conducted in 2008, with supporting pilot studies and analysis completed in 2010. Site visits were used for the survey in both operating departments and the sterile services departments (SSDs) that support them. Assistance was provided by the Health Protection Agency (HPA) and the service providers themselves. Independent and industry-based engineers specialising in surgical instrument decontamination played an important role, particularly in the survey of quality systems and engineering controls.

A series of pilots was established alongside the survey and continued to run subsequently, with the aim of investigating the efficacy and practicality of a range of methods for reducing prion transmission risk. Areas investigated include single (ie individual)-instrument tracking and tracing, keeping instruments moist after use (Great Ormond Street Hospital for Children NHST (GOSH)/ University College Hospital London (UCHL)/ Queen Mary University of London), updating the choice of instruments within sets to properly reflect the evolving procedures for which they are used (Newcastle upon Tyne Hospitals NHST), high sensitivity residual protein localisation and quantification (GOSH/ UCHL/ Queen Mary, Southampton University, Edinburgh University). Findings from the survey and experience gained during the pilot programmes have provided key parts of the evidence base informing the new guidance issued in Choice Framework for local Policies and Procedures (CFPP) 01-01.
Timing of publication

The timing for publication of this survey report has been set by the Department of Health (DH) so that an holistic picture can be presented to the reader by combining the 2008 survey visit findings with the subsequent work by the guidance implementation pilots. This enhanced document has been used as a significant part of the evidence base for CFPP 01-01, to which it is annexed; the publication of the survey work and guidance together makes it possible to deliver a more coherent policy and guidance package.

Main findings

The findings show that the great majority of centres are successfully implementing surgical instrument reprocessing quality system guidance. While an impact on prion removal or infectivity reduction is yet to be demonstrated directly, evidence from the pilots supports this assertion. There are positive findings on the benefits of keeping used instruments moist prior to decontamination and from the use of improved protein quantification techniques which have enabled the subsequent refinement of washing-disinfection procedures and detergent choice.

The survey evidence also suggests that certain aspects of decontamination guidance, outside the engineering standards and quality systems implementation, are better followed than others. In particular, the management and audit of instruments when they pass between operational teams, for example between SSD and operating theatre staff, are often weak. This is a key focus of the pilots as well as the CFPP 01-01 guidance.

Implementation of NICE IPG 196 (2006) guidance

Implementation of NICE IPG 196 (2006) ‘Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease via interventional procedures’ (NICE IPG 2006) guidance has not progressed as rapidly or fully as had been expected. Key aspects of the guidance, such as the much-enhanced integrity of instrument sets and the removal of the need for the use of supplementary instruments, are not yet commonly in place (Figure 1). However, flexible neuroendoscope use is much reduced, replaced by the use of rigid neuroendoscopes, in line with NICE IPG 196 recommendations.
The track-and-trace technologies, which enable individual instruments to be audited and retained in their sets, are only implemented and working in a small number of centres. An alternative approach, pioneered at Newcastle Teaching Hospitals NHST, based on redesigned and larger instrument sets as a means of eliminating the use of supplementary instruments, has been shown to reduce their use to negligible levels.

In addition, the NICE IPG 196 (2006) recommendation to introduce dedicated instrument sets to prevent children born after 1 January 1997 from being exposed to prion contamination during surgery have been implemented in very few centres. Where they have, this was often without accompanying measures to ensure good set integrity, so that overall risk reduction is not secured. Of the centres surveyed, only those that were also pilots have achieved the full risk reduction intended by NICE IPG 196 (2006).

Evidence suggests the letters from the Chief Medical Officer (CMO) in support of NICE IPG 196 guidance have raised the awareness of the need to implement the guidance. However, this has not raised the rate of actual implementation. The major pilot on this item of guidance was at Great Ormond Street Hospital.

**Implementation of ACDP-TSE RM guidance**

The guidance from ACDP-TSE RM on surgical prion transmission risk control for at-risk patient groups is, by contrast to the NICE measures, well implemented by the...
majority of centres surveyed. It is likely that this is exerting downward pressure on risks, at least from those patients with a known risk of prion infection.

**Decontamination process quality systems**

The analysis related to quality systems and their implementation shows a strong performance. The implication is that procedures and controls are sufficiently robust in all centres to permit a round of further improvement in decontamination-related risk control. This would include improved protein removal and the implementation of new ‘anti-prion’ decontamination technologies once their application is better understood.

**Operational practices and electrical safety**

Operational practices are a key aspect of decontamination and are central to maintaining a continuously high quality of product output. Most centres are compliant with their own local policies and procedures. However, a significant proportion of centres suffer from a lack of instrument and safety device testing equipment, such as that required for electrical safety checks on diathermy equipment, to ensure that equipment is safe for use. The concerns are especially with regard to electrical hazards from devices in direct contact with the patient.

**Staff training and development**

The survey suggests that most staff are trained to a suitable level in terms of the operation of the equipment they use, but that there may be considerable scope for broader training and professional development.

**Facilities for instrument decontamination and management**

The environment for decontamination and instrument management has not improved as rapidly as the decontamination equipment itself. Many centres have sub-optimal flow from dirty to clean and separation within this flow. Additionally, centres fail to provide such simple facilities as wash-hand basins within instrument inspection areas. Few centres have fully designated spaces for specific tasks,
particularly those related to storage. Ventilation of the environment used for instrument decontamination is often not compliant with existing guidance.

**Key recommendations**

Evidence from the survey strongly supports the view that the 30 selected centres produce sterile instruments as required by the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance. Although the quality systems and standards supported by pre-existing DH guidance are shown by the survey to be effectively implemented, many other guidance packages such as NICE IPG 196 (2006) are not. The following recommendations are therefore based on correcting the existing significant areas of non-implementation and applying further measures via the accompanying CFPP 01-01 guidance:

- Strengthen NICE IPG 196 (2006) implementation. Evidence from the pilot sites (see CFPP 01-01 Part A) supports the implementation of the further guidance in CFPP 01-01, published with this report. This includes the need for a greater emphasis on protein removal and prion risk-reduction aspects of decontamination;

- Carry out a local risk assessment for electrical instrument safety and calibration, with particular emphasis on diathermy and address any safety issues;

- DH to consult with ACDP-TSE RM on enhancing the use of the latter’s guidance now that good data on implementation has been established. ACDP-TSE RM guidance for neuro-, posterior ophthalmic and general surgery is referenced in CFPP 01-01;

- Suitably optimise the use of washer-disinfectors. Initial and ongoing research on protein removal in washing processes is well-supported by current quality systems implementation, making washer-disinfector optimisation both feasible and worthwhile in the working environment;

- Introduce audit programmes in all centres, particularly in those where implementation of NICE IPG 196 (2006) and ACDP-TSE RM guidance is being pursued;

- Consider repeating the survey in two or more years’ time, to examine the effect of implementing CFPP 01-01, as advised by learned bodies;
• Determine appropriate parameters for the physical environment, including ventilation of decontamination facilities, supporting the provision of further design guidance (see Health Building Note 13 – ‘Sterile services department’ for further information);

• Advocate such simple improvements as the better provision of wash-hand basins and operational protocols in order to raise hygiene standards in sterilization providers (see Health Building Note 13 for further information);

• Strengthen surgical instrument management, including the proposed new role of Surgical Instruments Manager within all surgical centres in acute care, with better protocols for implementation and audit, particularly for supplementary or loan set instruments. For high-risk procedures, a link to patient identity is necessary. The systems provided by NHS Connecting for Health and Coding for Success are suitable for this purpose;

• Introduce measures such as the improved audit procedures described in CFPP 01-01 Part A to reduce the likelihood of single-use instrument reuse due to migration into reusable instrument sets;

• Emphasise to providers the need to apply current guidance on disposal of single-use instruments (see ‘Safe management of healthcare waste’);

• Review single-instrument tracking and set structure. Pilots at GOSH have shown that single-instrument tracking is viable, whilst work at Newcastle upon Tyne NHST has successfully demonstrated an alternative or enhancement to single-instrument tracking via the use of larger instrument sets in clinical groups, described in CFPP 01-01 Part A;

• As part of a learning exercise from this survey, commercial contract terms should comply with current and evolving decontamination guidance and be addressed in arrangements for external surgical instrument decontamination services. Pilot work at Birmingham Children’s Hospital (see CFPP 01-01 Part A) where decontamination services are provided by an external commercial contractor is likely to be helpful here.
1.0 Introduction and background

DH medical device decontamination improvement policies have usually focused on secondary or tertiary ‘acute surgical services’, as this is where evidence suggests that the major risks of infection transmission - particularly by surgical instruments - exist. Much of this thinking was stimulated by continuing concerns over residual protein contamination following decontamination, and the possibility that human prions - specifically variant Creutzfeldt-Jakob Disease (vCJD) - could be transmitted in this way. The most recent guidance from NICE and ACDST draws renewed attention to the prion issues, with a particular focus on high-risk tissues, including those of the brain and the posterior eye.

In response to the concerns regarding prion risk, DH’s Gateway Review Estates and Facilities Division determined to carry out a survey on instrument management and decontamination in some 30 centres that provide high-risk tissue procedures in neuro- and complex posterior ophthalmic surgery.

The fundamental purpose of the survey was to determine the progress made by healthcare organisations in implementing NICE IPG 196 and Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathies Risk Management subgroup (ACDP-TSE RM) guidance contained in ‘Transmissible spongiform encephalopathy agents: safe working and the prevention of infection’. These measures are built upon the continued development of improved general surgical instrument decontamination, based on BSi/EN/ISO engineering standards and quality systems, the majority of which are now harmonised; this implies that these standards now agree in terms of detailed content across the respective standards organisations, thus removing previous conflicts and confusion over definitions.

A secondary goal of the survey was to help determine the risk of any possible further spread of human prions via surgical instruments. Additionally, the survey aimed to assess the centres’ compliance with decontamination quality systems designed to ensure satisfactory engineering within the use/ decontamination/ reuse cycle.

In 2008, DH carried out the field-work for the first part of a two-phase National Decontamination Survey (NDS). The survey was timed to serve the evidence-gathering programme for CFPP 01-01, which modernises decontamination guidance for acute sector services.
A series of pilots was run at three centres - GOSH / UCLH, London, Birmingham Children’s Hospital and Newcastle upon Tyne NHST - to test the protocols and techniques utilised for the survey. Subsequent to the completion of this survey round, steps were taken to convert these pilots to a new role. In this new role, the pilots have investigated means of addressing key areas shown by the survey to be in need of further development. DH has provided part funding to this new pilot work in which survey findings have been addressed by the formulation of new guidance which has been tested within these pilot centres at both scientific and practical levels. Within this report, new findings derived from these pilots are presented alongside those from the original survey work.

It should be stressed that the survey was carried out for scientific purposes, to assist in the gathering of evidence useful in determining the magnitude of risks related to any further spread of human prions via surgical instruments. The survey protocols were developed to provide a representative picture of national neuro- and posterior eye centres’ decontamination quality system effectiveness, rather than to examine individual trusts’ or service providers’ performance.

This report describes the decontamination survey process, findings and conclusions. It makes recommendations to improve the quality of surgical instrument provision and to reduce the risk of further spread of human prion diseases within the population of surgical patients.

The timing for publication of this survey report has been set by DH so that a full holistic picture can be presented to the reader. By publishing in 2012 it is possible to take the 2008 survey visit findings and combine them with the subsequent more detailed work by the guidance implementation pilots. This enhanced document has been used as a significant part of the evidence base for CFPP 01-01; the publication of the survey work and guidance together is seen as serving the needs of guidance users when making choices within the framework offered.

The decontamination and surgical communities will benefit from reading this report in full, to reassure themselves of the progress made in decontamination of reusable medical devices, particularly in respect of the drive to implement quality systems, which has been underway since the late 1990s. The report will support both the scientific community in establishing the direction of future research and DH in policy and guidance development.

The findings of the survey also provide a baseline against which to review implementation of DH and advisory committee guidance on decontamination, for the
assessment of future progress. Provisionally the survey is scheduled for repetition two years after the publication of this report.

1.1 Policy and guidance environment

The NDS report is informed by a range of policy documents and independent guidance from organisations such as DH, NICE, ACDP-TSE RM and ACDST. It has been further supported by CMO's correspondence.

1.1.1 Department of Health Policy and guidance

In 2007, DH published a policy summary on the decontamination of reusable medical devices in healthcare organisations (Department of Health (2007) ‘Clarification and policy summary – Decontamination of reusable medical devices in primary, secondary and tertiary care sectors’). This policy statement identified that decontamination services in healthcare establishments are required to provide a service in accordance with the EEC (now EU) Medical Devices Directive (MDD), which is adopted into UK law within the Consumer Protection Act as the Medical Devices Regulations (MDR) 2002/4 (subject to current revision).

In accordance with the philosophy set out in DH's policy document, Shifting the balance of power, and as further described in the 2007/8 NHS Operating Framework, responsibility for achieving acceptable standards of care delivery, including decontamination, lies with commissioners, individual trusts and provider organisations. The influence of this policy is seen in the locally-decided nature of the decontamination policies held by trusts and their service providers.

The MDR lays down a set of essential requirements that centre around ensuring that reprocessed devices, including surgical instruments, are safe and fit for purpose. In decontamination units, compliance is required in such key areas as the control of processes and the working environment. Another essential requirement for decontamination units is the use of a recognised quality management system, such as the standard BS EN ISO 13485:2003 Medical Devices. Compliance with these systems is rigorously investigated in this survey.

Quality standards define the required characteristics of products and services. In decontamination units, standards relating to quality systems, the working environment, safety, reliability and efficiency of surgical instruments and ancillary
equipment are particularly relevant. Decontamination of reusable medical devices is governed by a number of best practice quality standards and systems, whose implementation is key to ensuring that products are safe and fit for purpose. This approach forms much of the basis of CFPP 01-01 Parts A–E.

### 1.1.2 The Health and Social Care Act 2008

The Health and Social Care Act 2008 established the Care Quality Commission (CQC) to register, review, investigate and support improvements in healthcare provision. 'The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance' ('the Code') supporting this Act is aimed at reducing HCAIs and sets out how the CQC will assess compliance with Regulations made under section 20(5) of the Health and Social Care Act 2008. Healthcare organisations are specifically required by the Code to provide a safe decontamination service for reusable medical devices.

### 1.1.3 CMO’s letters

The CMO has to date published two professional letters ‘drawing the attention’ of centres providing neurological and posterior eye surgery to their responsibilities in implementing NICE IPG 196 (2006) guidance. The first letter, dated February 2007 reminded centres that they should be developing arrangements to implement NICE guidance and set out DH’s plans to issue further advice on decontamination in 2007. This advice is now incorporated into the CFPP 01-01 guidance package.

A second letter followed in March 2008 highlighting the need for all centres offering neurological and posterior eye surgery to urgently review their progress on the implementation of NICE IPG 196 (2006) guidance. This letter made reference to findings from the NDS pilot studies in relation to how NICE recommendations were being implemented. It expressed concerns about instrument movement (‘migration’) between instrument sets, and about the need to reduce the use of supplementary instruments which cannot adequately be tracked. The letter also stressed the need for centres to procure new instruments for exclusive use in surgery on children born after 1 January 1997 and identified key implementation steps.
1.1.4 Independent guidance

Independent guidance from NICE, ACDP-TSE RM and ACDST has helped to shape the NDS 2008/10.

NICE is an independent organisation responsible for providing national guidance on health promotion and on the prevention and treatment of ill-health. It produces guidance in three main areas: public health, health technologies and clinical practice.

In November 2006, NICE issued full guidance to the NHS in England, Scotland, Wales and Northern Ireland on patient safety and reducing the risk of transmitting CJD via interventional procedures (NICE IPG 196). This guidance is referred to in the CMO letters cited above. The purpose of this guidance was to further reduce the theoretical risk of iatrogenic spread of CJD via surgical instruments and neuroendoscopes. The recommendations relate to those instruments which have or may have come into contact with ‘high-risk’ tissues – that is, those beneath the dural membrane (intradural operations), on the retina of the eye and on the optic nerve. These tissues are classified thus as a reflection of the distribution of vCJD infectivity within the body’s tissues, should such infection be present.

Note

Within this report reference is made to both CJD and vCJD. Where the term CJD is used, the intention is to cover sporadic and familial as well as variant disease. Where vCJD is used, a specific reference to variant disease is being made.

The guidance made specific reference to keeping a separate pool of new neuroendoscopes and reusable surgical instruments for high-risk surgery on children born since 1 January 1997 who have not previously undergone high-risk procedures. These children are unlikely to have been exposed to Bovine Spongiform Encephalopathy (BSE) in the food chain, or CJD via a blood transfusion.

ACDP is a UK-wide non-departmental public body. Its remit is to advise the Health and Safety Executive, ministers and the Department of Environment, Food and Rural Affairs (DEFRA) on all aspects of the hazards and risks to workers and others from exposure to dangerous pathogens. It is involved in the production of guidance relating to safety at work and the protection of public health, as well as advising government on the implementation of policy and legislation relating to specific pathogen risks and their impact.
As part of its remit, ACDP-TSE RM produced the guidance document ‘Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection’. This guidance and the associated annexes aim to minimise the risk of transmission of CJD and vCJD. It was first published in June 2003 and has evolved in the years since, with new annexes being added and current guidance being updated as further scientific information becomes available or new policy decisions need to be reflected.

ACDST was a DH advisory committee whose purpose was to take forward for potential practical application the body of research relating to the decontamination of surgical instruments, with the emphasis on protein removal and prion deactivation. It brought together members of the scientific, clinical and engineering communities to focus on the transfer of knowledge from the research environment into practising surgical instrument reprocessing facilities and services. The committee was disbanded at the end of 2010 with the grateful thanks of DH. A new group within the ACDP structure is in the process of formation and will deal with risk management in this important area.

In autumn 2006 ESAC-Pr (as it was then called) published a report which provides background evidence and guidance on changes in surgical instrument provision and decontamination operations aimed at reducing the possible spread of prion disease via surgical routes. Its recommendations reinforce the NICE IPG 196 (2006) guidance.

### 1.2 Aims and objectives of the NDS 2008/10

The survey is based on the assertion that risk control, based on the use of quality systems and EN/BSi/ISO standards from existing guidance, together with investment and development programmes, has raised performance in instrument management and decontamination to a level such that further risk-reduction strategies, particularly those related to enhanced instrument quality and reduced prion transmission risk, can now be successfully applied.

The survey aims to assess the progress of measures put forward by DH, NICE and ACDP-TSE RM to suppress actively the risk of prion transmission, in terms of both guidance implementation and further development.
The aims and objectives of the NDS 2008/10 were:

a. To capture information relating to quality systems for medical device and surgical instrument reprocessing;

b. To start investigating the discouraged reuse of single-use instruments and neuroendoscopes, by examining the nature of the migration of surgical instruments throughout or into the decontamination lifecycle;

c. To encourage rapid implementation of NICE IPG 196 (2006) guidance;

d. To specifically examine the implementation of NICE IPG 196 (2006) within the specialist centres surveyed.
2.0 Methodology

The NDS 2008–10 was carried out in accordance with DH scientific rules, and focused on a sample of 30 centres providing high-risk tissue procedures in neurological and posterior ophthalmic surgery in England. The appropriate learned and professional bodies advised on the sample selection process, with the aim of capturing a large proportion of those centres making substantial contributions to surgery in the high-risk tissue areas. Participation in the survey was voluntary and not performance-related. Only one centre declined the invitation. The subsequent guidance development pilots have operated at three of the 30 centres mentioned.

Note:

In the performance of this survey some 30 active sites performing neurosurgery and/or associated decontamination procedures were visited. However, this equates to only 28 complete operational units, owing to a combination of trust mergers and the use by more than one trust of a single decontamination facility.

Care was taken to include all of the current arrangements for decontamination service provision. In addition, the special considerations given in NICE IPG 196 (2006) guidance to surgery on young children are reflected in the inclusion of specialist children’s centres within the survey.

The survey was conducted via a questionnaire which was devised to gather observational data and keep an objective record of the 30 centres’ policies and operational practices as they apply to standards-based quality systems for medical devices and surgical instrument reprocessing. In addition, the survey results are helping DH to start evaluation of the rate of reuse of single-use instruments and neuroendoscopes as well as the nature of migration of surgical instruments between their ‘parent’ sets throughout the use / decontamination cycle.

Research took place in the SSDs and operating theatres, with the data collected by joint research teams comprising independent researchers, assisted by local staff. The analysis was conducted by a joint DH / HPA team primarily using a figure-of-merit (%) grading system applied to a relational database holding the survey results in anonymous form.
2.1 Scope

The development of the questionnaire and the analysis of the findings are both aligned to a risk-reduction philosophy. The questionnaire was developed with advice from learned and professional bodies. The 30 healthcare service providers (mostly NHS trusts) who took part in the survey formed a clear majority sample of the surgical centres performing high-risk tissue surgery and their decontamination service providers, including those providing paediatric surgical services.

The survey is not intended to be a comprehensive review of decontamination across the NHS. Instead, it covers many aspects of surgical instrument provision, use and decontamination, including work taking place in operating theatres or provided by support services – primarily NHS or commercial sterile service units. The new large centres formed as a result of the National Decontamination Programme are represented within the survey.

2.2 Questionnaire development

The survey was undertaken using a modern balanced questionnaire, and the data collected in an MS Access database. A total of 1010 questions were developed, grouped to take account of the decontamination lifecycle, decontamination quality systems, NICE guidance and advisory committee recommendations. Whilst the majority of questions required a binary yes/no answer, some required a value judgement answer. Hidden safeguards were also included, for example, through the duplication of questions. Several questions in each category were asked a number of times, but phrased in a different way. Some questions link directly to EN standards, which themselves inter-relate.

The questionnaire was initially designed to support the survey process, based as it was on visits and observation. The structure of the survey was then reviewed by a sub-group of the ESAC-Pr committee and the questions subsequently regrouped into Quality System Categories for simple comparative analysis.

2.2.1 Survey data questions

Twelve core analysis questions were developed with advice from ESAC-Pr, ACDP-TSE RM, committee chairs and experts from a range of learned and professional bodies, to help interpret the survey data. These questions seek to answer whether
the investment and development programmes run to date, together with DH guidance and the applications of measures recommended by DH, NICE and ACDP-TSE RM, have raised performance in instrument management and decontamination, giving at least some reduction in prion transmission risks.

The 12 questions are:

1. Has NICE IPG 196 (November 2006) guidance to reduce the risk of transmitting CJD and vCJD been effectively implemented across the 30 specialised centres surveyed?

2. Have the selected centres specifically implemented NICE guidance and CMO requirements to reduce the use of supplementary instruments?

3. Have the special measures published by ACDP-TSE RM, designed to reduce risk from persons likely to be a source of CJD and vCJD, been implemented across the specialised centres?

4. Are the centres’ quality assurance systems (engineering standards) adequate to permit further developments in risk reduction?

5. Where high quality systems implementation standards are observed, do they extend beyond the mainstream SSD to the operating theatre and on to other less prominent areas of surgical service delivered within the institution?

6. Can the centres respond and adapt to changes in national policy, guidance and European Norms (ENs) which affect surgical instrument decontamination?

7. Steam sterilization is currently the main method by which sterility and prion deactivation are achieved; Are ENs for this area effectively implemented? Have guidance measures to improve this area been effectively implemented?

8. Are standards of validation, testing and record keeping in SSDs adequate to support robust audit and provide a platform for further development?

9. Have centres that offer paediatric services put safeguards in place to minimise the risk of young patients presenting for surgery being exposed to the CJD or vCJD infective agent, particularly for those born since January 1997?

10. As effectiveness of steam sterilization is dependent upon the cleanliness of the instruments prior to sterilization, have cleaning practices been effectively implemented?

11. Is the physical working environment within SSDs adequate to support long-term improvements to their services?

12. Are staff involved in decontamination appropriately trained?
2.3 Research teams

The on-site survey was carried out by teams of four researchers comprising independent researchers, with sterile services / engineering and clinical backgrounds, plus one additional researcher with infection control experience contributed by HPA as an independent observer of the survey process.

Research participants from the centres were seen as an integral part of the team, as the survey process owners, and their contribution ensured the seamless conduct of the on-site survey. Steps were taken to ensure that staff from SSDs, theatre and engineering disciplines were available to participate on the scheduled survey date.

2.4 Data collation

The research teams collated the data using MS Excel or Access, and transmitted it securely to a central point. The results were then imported into a Master MS Access fully relational database so that analyses could be carried out and reports generated.

2.5 Figure-of-merit (FOM) analysis

The analytical scoring system was based on a FOM approach. A FOM is a quantity used to characterise the performance of a device, system or method relative to its alternatives. The main advantage of this technique is that it is able to reflect not only the relative importance of applied methods – in this case, the decontamination processes undertaken by trusts and/or their suppliers – but also allows emphasis of key steps in the decontamination process.

FOM analysis requires the use of weighting factors to establish the relative importance of each item under review, in this instance in risk-reduction terms. DH assigned each survey question to the appropriate risk-reduction Quality System Category, based on EN standards. A special sub-group of ESAC-Pr weighted each of these Quality System Categories on a scale of 1 to 5, according to their relative importance in terms of protein removal and / or prion deactivation value.

The FOM (%) Score and FOM Rating are two key outputs from the FOM scoring system.
The FOM (%) Score provides a measure of the merit or benefit suggested by each survey answer. A score of 100% for a specific answer indicates that the maximum merit (or benefit) was achieved for that answer. However, it is not possible for a centre to score 100% over a complete survey, due to the way the questionnaire is structured. A score of 87% should be considered as approaching the maximum possible at the time of the 2008 survey visits. As the guidance is revised and this survey repeated it will become possible for centres to approach a 100% score. This analytical strategy leaves room for future improvement and provides for the increased risk reduction effect of future guidance.

The FOM Rating grades each FOM (%) Score using an A to E scale, intended to assist with the interpretation and comparison of the survey results. As discussed above, an A rating could not be achieved in the initial survey but should become possible after the introduction of new technologies.

Table 1 illustrates how the FOM Rating is derived from the FOM % Score. The detail and calculation of the FOM (%) Score can be seen in Annex 1.

<table>
<thead>
<tr>
<th>FOM (%) Score</th>
<th>FOM Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>88 or above</td>
<td>A</td>
</tr>
<tr>
<td>72–87</td>
<td>B</td>
</tr>
<tr>
<td>60–71</td>
<td>C</td>
</tr>
<tr>
<td>49–59</td>
<td>D</td>
</tr>
<tr>
<td>Below 49</td>
<td>E</td>
</tr>
</tbody>
</table>

The survey data are anonymised in any output reports so that the individual trusts and private service providers are not identified. The trusts involved have been provided with a copy of their own report, which includes an explanatory note outlining the presentation of results and the FOM % Score.

2.5.1 Quality System Categories

DH, with the assistance of ESAC-Pr, agreed a set of Quality System Categories to facilitate analysis of the survey results, and assigned each survey question to an appropriate category. This approach, in effect, groups the EN, ISO and BSi standards
in operational terms (see section 2.2), and provides a platform for prion transmission risk reduction (see Annex 1).

Weighting factors are scaled from 1 to 5. A weighting of 1 indicates that a survey question is of minimal relevance in terms of prion removal and deactivation. A weighting of 5 indicates that the question is of the highest relevance in terms of prion removal and deactivation. The survey's weighting factors are illustrated in Table 2.

Table 2. Quality System Categories relevant to prion removal and deactivation

<table>
<thead>
<tr>
<th>Quality System Category</th>
<th>Relevant guidance</th>
<th>Relevant EN/ISO standards</th>
<th>Weighting factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washing/dischinfection</td>
<td>HTMs 2030</td>
<td>Washer-disinfectors: BS EN ISO 15883 1/2/3</td>
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<td>HTM 04-01</td>
<td>Water supply: BS 6700</td>
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<td>Inspection</td>
<td>HTM 01-01 Part A</td>
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<td>Sterilization/steam</td>
<td>HTM 2010; HTM 2031;</td>
<td>Steam sterilizers: BS EN 285 (Large) BS 13060 (Small) BS EN 556 1/2</td>
<td>5</td>
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<td>Record keeping</td>
<td>HTM 01-01 Part A; Record Management Code of Practice (2006)</td>
<td>Medical devices, quality management systems: BS EN ISO 13485</td>
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<td>Instrument tracking</td>
<td>HTM 01-01 Part A; GS1 Coding For Success (2007)</td>
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<tr>
<td>Instrument quality control</td>
<td>ESAC-Pr 2006; MDD – Essential Requirements</td>
<td>Medical devices, quality management systems: BS EN ISO 13485</td>
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<td>Staffing/training</td>
<td>Institute for Decontamination Sciences (IDSc) initiative; IHEEM Authorising Engineer (Decontamination)/AE(D)</td>
<td></td>
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<tr>
<td>Management controls</td>
<td>HTM 01-01 Part A; CQC; MHRA notified body</td>
<td>Medical devices, quality management systems: BS EN ISO 13485</td>
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</table>
Survey questions with a weighting of 1 are considered ‘non-relevant’ Quality System Categories in prion risk-reduction terms. They therefore fall into the general body of measures concerned with obtaining a clean, sterile instrument product following decontamination. These questions are not included in the trust reports (Table 3) but do provide a platform for general improvement and modernisation in decontamination services. They have therefore been included in the analysis.
2.6 Statistical reliability – data acquisition and database quality

The validity of any survey is dependent upon the reliability of the data collected. For this survey, the large volume of data collected on each centre does increase the risk of sundry error. The reliability of the data has therefore been assessed using two approaches: data type enforcement and inverted logical questions. Data type enforcement checks that the right type of answer is assigned to the right type of question – for example, ‘yes/no’ to a logical or binary question. Inverted logical questions act as a check, in that the correct or positive-scoring answer is a ‘no’.

Samples of five selected questions were examined. Out of those five, one question elicited a single positive response for the majority of supplementary questions, when the original response was either ‘no’ or ‘not applicable’. It is not possible to determine which of these represents an error.

Additional recoding rules have been necessary to remove the vast majority of problems that were caused by an initial lack of data type enforcement prior to the construction of the present database. It is difficult to quantify the errors now remaining in the database, but these are estimated to be in the order of less than 1% of the entries, which is unlikely to introduce any major issues concerning the overall reliability of the results.

2.7 Scope of the data

All 30 of the centres that agreed to take part in the survey completed it. All of the data collected during the NDS 2008/10 were included in the scoring process, except for the following:

Answers to questions with an FOM weighting of 1 have not been scored and are excluded from trust reports related to prion transmission risk.

DH considers all survey questions assigned a Quality System Category weighting of 1 to be of minimal relevance in terms of prion removal and deactivation. Their exclusion does not affect the scores achieved. However, many of these considerations are of key concern in the conventional business of cleaning and sterilization. To this end, three broad analysis questions related to cleaning practices, staff training and working environment have been included in this report and were analysed in detail for each individual trust. These analyses were sent to each participating trust on a confidential basis, the reports covering the work of that centre only.

The details of the FOM scoring and analysis can be found in Annex 1.
2.8 Data conversion and impartiality

In some cases, researchers recorded a binary 'yes/no' answer against a numerical question, or a numerical answer against a binary question. A conversion process was therefore required for a total 1506 answers or instances, a small proportion of the total. DH devised the decision tables to determine the appropriate method of conversion for each possible case. The amended answers are recorded in Annex 1.
3.0 Findings

The FOM percentage scores and rankings for the centres surveyed are presented in Table 4.

Out of the 30 centres surveyed, 19 achieved a rating of B, 10 achieved a rating of C and 1 an E rating, as outlined in Table 4 and further discussed below. The E-rated centre has subsequently closed and has been replaced by a modern facility.

**Note**
As the number of centres visited within the survey is approximately 30, then for general purposes the resolution of survey results is 3% of the total. However, because some centres use more than one decontamination service the definition of a single instance in the survey is variable. On this basis the maximum number of ‘centres’ would be 34. In addition, many of the results presented in this survey report are multi-factorial, bringing together the outcomes from several questions. It is for this reason that results quoted in the text do always follow the 3% resolution which might otherwise be expected.

When considering these results, it is important to remember that the scoring system is designed to take account of the maximum attainment achievable when the new CFPP 01-01 guidance is implemented in high performing centres. At the time of the survey, many of the CFPP recommendations were not available, which limits the maximum possible score; a score of 87% should therefore be considered as approaching the maximum possible at the time of the survey (see section 2.5).

The large proportion of trusts and decontamination providers gaining scores in the upper categories is indicative of a national trend toward satisfactory implementation of the quality systems and other supplementary material covered in HTMs 2010 and 2030 as well as the decontamination manual.

DH sees the above as providing a sound basis for the development of additional risk control measures within a choice framework, as implemented by CFPP 01-01. The use of a choice framework reflects a mature decontamination environment which is capable of the decision making and further development required.

Corrected for a maximum attainable score of 87, the lowest score seen (excluding the one centre which subsequently closed) was 69% of the attainable maximum. This suggests that even the ‘poorest’ centre has by the measurements provided in this survey performed well.
<table>
<thead>
<tr>
<th>Site number</th>
<th>FOM (%) score</th>
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<tr>
<td>30</td>
<td>47.4%</td>
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*centre subsequently closed*
3.1 Survey data analysis and main findings

For the sake of clarity, the survey data questions and analysis are listed in their original numerological order.

1. Has NICE IPG 196 (November 2006) guidance to reduce the risk of transmitting CJD and vCJD been effectively implemented across the 30 specialised centres surveyed?

NICE IPG 196 (2006) guidance identifies the steps that should be taken to reduce the risk of transmitting CJD and vCJD via surgical procedures on high-risk tissues – those beneath the dural membrane, on the retina of the eye and on the optic nerve. These steps include maintaining instruments within their sets (which extends to supplementary instruments), using rigid autoclavable neuroendoscopes and single-use accessories, and using separate pools of instruments for children born after 1 January 1997.

Instrument leakage

The estimated rate of leakage of surgical instruments between sets, particularly in respect of high-risk tissue contact, is 23.7% (that is, more than one in four instruments migrates into a different set) across the reported survey as a whole. However, caution is needed as this degree of migration may occur in a sample taken across a number of surgical procedures and associated decontaminations. The figures should not therefore be interpreted as 23.7% per cycle of use and decontamination. Subsequent work within the pilots has however confirmed that over a number of procedures, a quarter of instruments do indeed migrate, though it is important to understand that the use of supplementary instruments is included within this overall figure.

The data identifies that the risk of mixing instruments between sets is greater during reprocessing (10.3%) than when in use (4%). Subsequent investigation led by the pilot site at Newcastle has demonstrated that the bulk of this migration relates to supplementary instruments. The migration has two components: firstly the movements between sets of the supplementary instruments themselves and secondly the mis-identification of these instruments, meaning that other instruments are wrongly moved between sets. On return from reprocessing, 41% of sets have at least one defective or missing instrument, and this has serious implications for maintaining the integrity of the set. In general, 34% of migration of instruments can be detected using the present routine audit and inspection processes.
Record keeping and tracking

All centres (100%) have an IT-based instrument set track-and-trace system in use, as outlined in Health Service Circular 2000/032, and 47% of them are able to track at least some reusable single instruments. GS1 coding or a comparable system has been implemented in 35% of centres and 57% keep a record of their instruments’ usage for both neurological and posterior eye procedures, and so are able to track their history at least at the set level. In relation to individual instrument marking, 17% of surveyed centres have uniquely identified single-use instruments using techniques similar to those described in DH ‘Coding for Success’, which implies the use of the GS1 scheme. However, 32% have a GS1 related policy in place. It should be noted that the timing of the survey was such that the ‘Coding for Success’ publication may not have been accessible to all of the departments visited.

Where small or benchtop vacuum and air displacement steam sterilizers are used, traceability of sterilized instruments and devices is shown to be inadequate: those centres using vacuum sterilizers scored 0% for single instrument tracking and those with air displacement scored 17%. However, these devices are retained for contingency purposes and are little used in routine decontamination.

Instrument streaming

Steps are being taken to ensure that instruments which come into contact with high-risk tissues are separated into a discrete administrative stream and kept isolated to prevent any possible mixing with instruments used for other tissues. This does not imply the use of dedicated plant and equipment for their reprocessing, though this is feasible in some large centres. The survey shows that 41% of centres have the capacity to twin-stream their decontamination functions in this way using administrative measures. Three centres use administrative streaming for other applications including the protection of sets used for special purposes such as some areas of ENT surgery. In 32% of centres, administrative instrument streaming has been introduced to separate high-risk from general acute surgical instruments.

70% of instruments are recorded as being kept in sets during use and whilst being processed. However, centres experience difficulty in maintaining complete sets when instruments are taken away for repair. The survey identifies ambiguous practice in this area, with 28% of centres appearing to suspend the use of a set when instruments are sent for repair or cannot be traced. However, the data also suggests that 96% of centres continue to use incomplete sets when necessity demands.
Practice regarding replacement instruments also varies: 65% of centres replenish the set from stocked instruments where these types are also used in general acute surgery; following repair, 59% return the instrument to the tray from which it was removed. The remainder place it back into general acute surgery pool. This latter practice presents an additional risk of prion transmission, and has been advised against. CFPP 01-01 Part A offers new guidance in this area.

Neuroendoscopes

NICE guidance on neuroendoscopes is adhered to in 72% of centres, which use rigid autoclavable neuroendoscopes whenever possible. All accessories used through neuroendoscopes should be single-use and 64% achieve this aim. These relatively good results are helped by clinical practice trends, which favour rigid endoscope use.

Single-use instruments

While NICE did describe but not specifically recommend the single-use option, all centres (100%) have a policy in place that permits application of single-use instruments where clinically appropriate. In addition, 37% of these regularly audit and document in order to reduce the risk of unintended reuse of single-use instruments. However 3.3% (one centre) reuse single-use supplementary instruments.

This finding, although related to only a single centre, is evidenced as part of a larger picture by correspondence to DH. In light of this interest and the legal status of reprocessed single-use instruments, DH will review its policies in consultation with MHRA. This does not, however, imply a relaxation of the current position in which the DH considers those carrying out reprocessing as in effect becoming the manufacturer of the reprocessed instrument.

2. Have the 30 selected centres implemented NICE guidance and CMO requirements to reduce the use of supplementary instruments?

The 2008 survey visits show progress overall, in that 32% of neurological and posterior eye surgery centres have implemented the guidance relating to supplementary sets in policy, this includes those using the strategy proposed by Newcastle. Some centres (48%) have implemented the guidance partly by using single-use
instruments as part of their approach. NICE did not specifically recommend this option.

However, if it is accepted that the Sheffield University risk study which underpins the NICE guidance essentially demonstrates that there is a relationship between set integrity (or the avoidance of leakage of instruments between sets) and the risk of downstream transmission of vCJD and possibly other prion diseases, then the Newcastle scheme offers much. The recorded instances of instrument leakage, including the use of supplementary instruments, in the subsequent pilot study commissioned by DH show that the reduction in leakage attained is difficult to equal by the use of the single instrument tracking to which NICE did specifically refer.

Where supplementary instruments are used, 83% of the centres surveyed report that they are dedicated to central nervous system (CNS) surgery though this includes the spine as well as the high-risk tissues of the brain. Of the remaining centres (17%) using supplementary instruments from other specialities, 67% use ENT, 50% use gastro-intestinal, 44% use general, 68% use maxillo-facial, and 64% use spinal. Only 11% use supplementary instruments from ophthalmic, including posterior ophthalmic. A small number of centres use supplementary instruments also used in orthopaedics, paediatric, thoracic, cardiac, transplant, vascular, obstetrics, dental, genitourinary and gynaecology.

**Note**
The above issue was addressed in a letter from CMO to all relevant providers which drew attention to the substantial importance of ensuring that supplementary instruments are not used in surgery to high vCJD transmission risk tissues. DH has investigated this issue further through a pilot study with Newcastle Teaching Hospitals NHST. In this study, the prevalence of supplementary instrument use was investigated within neurosurgery specifically. At the outset it found that the rate of supplementary instrument use was substantial, with virtually all procedures being affected.

DH’s protocol called for the use of single instrument tracking as a device to monitor and counter this potential source of significant risk. However, after early investigation the Newcastle trust elected to pursue an alternative approach in which the contents of each neurosurgical set were compared to the clinical need. This showed that surgeons were not using a proportion of each set’s contents, whilst other supplementary instruments were routinely required. In addition, the sets could not always be quickly and easily identified, particularly within the operating theatre.
The project then progressed to a thorough investigation of set contents, resulting in a review and a move to new set structures carefully matched to the needs of the surgeon. The sets are colour-coded to make identification easy at all times and are also somewhat larger than a conventional set in the same clinical area. The larger nature of the new sets means that some are split into several trays in order to make handling easier.

The rate of supplementary instrument use within neurosurgery at Newcastle has subsequently fallen to negligible levels.

3. Have the special measures published by ACDP-TSE RM, designed to reduce the risk from known or suspected CJD and vCJD carriers, been implemented across the specialised centres?

The survey showed that 93% of centres with specialist interest in neurosurgery and/or posterior ophthalmics have protocols in place for risk control when working with patients at increased risk of vCJD owing to large numbers of blood transfusions, tissue transplants, etc. Of these, 54% centre the protocol on an admissions questionnaire which is applied across all high-risk tissue surgery. Other centres use questionnaires which are routinely related to inpatient care. The full use of ACDP-TSE RM guidance Annex J is in place at 68% of centres.

Guidance on the use of neuroendoscopes with respect to at-increased-risk patients has been introduced in 64% of centres. 93% of centres take an approach which is clearly recognisable as being related to the ACDP-TSE RM. Of these centres, 38% kept neuroendoscopes used on at-risk patient exclusively for reuse on that patient.

The survey data does not permit easy identification of the neuroendoscopes against the technical procedures in which they are used. The evidence suggests that rigid neuroendoscopes are being reprocessed by conventional steam sterilization where appropriate.

The implementation of ACDP-TSE guidance has been looked at by a number of bodies with varying results. A recounting process on this survey showed that at initial contact many of the centres involved were not able to respond to questions on ACDP-TSE RM guidance – at approximately half the centres visited the survey team had difficulty in identifying the responsible person in respect of this form of risk control. However, by the latter stages of the survey visits, responsible officers had often been located and in consequence reliable results obtained.

CFPP 01-01 therefore addresses this matter with specific advice on relevant duties.
4. Are the 30 centres' quality assurance systems adequate to permit further developments in risk reduction?

Independently-assessed quality systems are in place in 77% of centres. Over 85% of centres show fully satisfactory records on decontamination equipment validation and maintenance. The use of EN standards and Quality Systems is clearly evidenced in 82% of the institutions visited. The majority of these specialised centres are therefore well placed to build upon current quality controls in the implementation of new instrument management and decontamination approaches. This additional guidance relates to the management of surgical instruments at every stage in their use, transportation, decontamination and storage. The common elements across these functions, such as record keeping and the need for trained/skilled operators are particularly emphasised. This is broadly an encouraging result, though there is an implication that just under a quarter of centres still have substantial work to do if they are to meet the requirements of CFPP 01-01.

5. Where high quality systems implementation standards are observed, do they extend beyond the mainstream SSD to theatre and to other less prominent areas of surgical service delivered within the institution?

In the small number of centres that use small or benchtop sterilizers, almost all quality standards scored 100%. There are procedures in place in 100% of centres that use small or benchtop sterilizers to ensure that re-commissioning is undertaken if a review of records from routine monitoring, periodic testing and performance requalification indicates unacceptable deviations from data observed during validation. There are, however, some differences in standards between vacuum and air displacement benchtop sterilizers.

Vacuum steam sterilizers

The maintenance scheme, including procedures and records, is reviewed periodically by a designated authorised person in 100% of centres this includes annual revalidation. However, only 50% of them retain maintenance records securely as part of the quality system records. A higher percentage – 75% – document the procedure for maintenance tasks and the frequency at which they are carried out, but this remains an area for improvement. Another cause for concern is in the calibration of recording instruments used for the validation and routine testing of sterilizers, where just 50% of centres state that there is an effective system in place.
Air displacement steam sterilizers

In 67% of all centres with an air displacement steam sterilizer, a designated authorised person (AP) reviews the maintenance scheme, including procedures and records. This meets one of the core requirements on this group set out in CFPP 01-01 A. However, all of the centres visited, which use this equipment, have a local policy in place and carry out annual revalidation.

The same proportion (67%) has a procedure in place to check that the sterilizer is used only when all specified maintenance tasks have been satisfactorily completed and recorded.

Other sterilizers: endoscope reprocessors

‘Other’ sterilizers are used in 10 centres (12 units) (33% of those visited) for sterilizing or reprocessing endoscopes which cannot be decontaminated in a steam sterilizer.

Only 24% of these centres have been subjected to a formal documented validation programme in line with HTM 2010. This is not surprising, as these sterilizers were plasma-augmented chemical sterilizers, rather than the steam sterilizers subject to the main thrust of HTM 2010. However, 88% of centres did have another formal documented validation programme, such as a manufacturer-based validation or certification programme.

Monitoring checks are carried out in 93% of centres on annual revalidation. Of concern is that only 50% of ‘other’ sterilizers have a maintenance contract. However, 87% of the surveyed centres state that they plan and perform preventative maintenance in accordance with documented procedures, while 63% specify and document both the procedure for each maintenance task and the frequency at which it is carried out.

Only 31% of centres have procedures in place for recommissioning, should deviations be found during validation or upon the review of records. In only 44% of centres are commissioning, performance qualification, re-commissioning and performance re-qualification assigned to a designated person who has appropriate training and experience, and who may be a suitably qualified test person. These findings may reflect the lack of personnel trained in this technology outside
Small and benchtop sterilizers: main findings

- Quality systems and standards. In the centres where small or benchtop sterilizers are used, there continue to be issues with ensuring that uniform quality systems are in place. This confirms the findings of other reports, particularly those from CQC. Despite this, almost all quality standards scored 100%.

- Maintenance records. Only 50% of the centres using vacuum sterilizers retain maintenance records securely as part of their quality systems records. Only 75% document the procedure for maintenance tasks and the frequency at which they are carried out. This is an area for concern.

- Air displacement sterilizers. In relation to air displacement sterilizers, the maintenance scheme (including procedures and records) is reviewed periodically by a designated AP ‘Sterilizers’ in two-thirds (67%) of all centres with such equipment.

- Small and benchtop sterilizers - validation. While ‘other’ sterilizers, including small and benchtop types, are most often not validated in accordance with HTM 2010, 88% of them did have another formal documented validation.

- Small and benchtop sterilizers - recommissioning. Recommissioning of other small or benchtop sterilizers is often poor, both in terms of procedures and the availability of appropriately-trained staff to carry out the work.

6. Can the centres respond and adapt to changes in National Policy, guidance and European Norms which affect surgical instrument decontamination?

The assumption made in this analysis is that those with good standards of quality system development and guidance compliance have created a strong platform from which further developments can be made with little risk that the inherent cohesion of the process will be compromised.

In relation to quality assurance systems, the survey identified that an independently-assessed quality system is in place in just over three-quarters (77%) of centres (see Question 4). Of the remaining 23%, it may be that at least some are proceeding in a satisfactory way using alternative risk control measures but this cannot be
confirmed from the available data. However, 93% make use of quality systems which accord with EN ISO 13485: 2003. Amongst other considerations, the guidance given in CFPP 01-01 is aimed at ensuring that those centres with significant deficiencies in their formal QA systems will address the issues and so create a sound platform for further progress.

Over 93% of centres have a system in place to ensure that medical devices (surgical instruments and endoscopes) and suppliers are reviewed to ensure that the products used comply with EN and BSI standards.

Quality systems records is deemed reliable where equipment is maintained with validation records to demonstrate a satisfactory performance. In general, maintenance standards have been good, albeit requiring improvements to documentation and record keeping.

Validation of washer-disinfectors of all types has been good. 97% maintain validation reports and records on the calibration of test instruments. Whilst 97% of centres carry out an annual revalidation on their major systems (see Question 7), arrangements for recommissioning are sometimes poor, with just 55% of SSD-based equipment and 67% of other small or benchtop sterilizers being recommissioned and retested where required as a result of a review of records (see Questions 5 and 8). Only 44% of centres assign revalidation to a designated person with appropriate qualification and experience. These variable results would suggest that for some centres, improvement is required in quality systems as part of gaining full advantage from the new guidance.

Local observations reported by 47% of centres visited suggested that the test soils in use did not represent the surgical soiling seen in terms of difficulty in removal.

Environmental standards provide the basic platform for both quality assurance procedures and quality systems to develop. Most centres scored 80% or above on environmental standards, that is, the building design and facilities which support the decontamination process (see Question 10), although there were areas for improvement, in particular in the provision of storage for sterile products, effective ventilation and facilities for the use and maintenance of test equipment. Beyond this there are significant failings in the provision of hand-washing facilities, particularly in respect of inspection areas where the 01-01 guidance calls for higher standards, similar to those found on wards. Further development in these areas is dependent upon addressing the identified shortfalls so that the recommendations contained in CFPP 01-01 can subsequently be accommodated.
Of the centres surveyed 79% have existing arrangements for liaison between de-
contamination and control of infection staff in regard of risk control and the NICE
guidance.

The survey evidence suggests that most centres are now able to implement nation-
al policy, HTM guidance and international standards affecting surgical instrument
decontamination in an efficient manner. However, the challenge is identified as sig-
nificantly greater when guidance from bodies such as NICE and advisory commit-
tees - including ACDP TSE WG - is to be implemented for risk reduction purposes.
The proposed introduction of the Surgical Instrument Manager role and the move
from the HTM structure to the new CFPP is intended to support both commissi-
oners and care providers in the adoption of this additional tier of recommendations.
The CFPP guides commissioners, quality inspectorates and service providers in a
fashion which offers choice and permits those with a strong basic quality system to
take full advantage of this attribute.

7. Steam sterilization is currently the main method by which sterility and prion deactivation
are achieved:
Are ENs for this area effectively implemented? Have guidance measures to improve this area
been effectively implemented?

Steam sterilization is essentially based on parametric discharge, that is steriliza-
tion of instruments may be assumed provided the recommended temperatures,
pressures and durations, etc., have been attained during the process. Much of this
depends on the sterilizer being well-maintained and validated. Validation in this
context is applied to the sterilizer cycles actually used in the local centre concerned
and demonstrates, to the satisfaction of an independent AE (D), that the machine is
attaining the required values for each of the parameters discussed.

Maintenance of equipment in SSD

The great majority of SSD centres (92%) have a service level agreement in place
for the maintenance of steam sterilizers. In addition 88% keep documented proce-
dures for each maintenance task and for its frequency. Of these, 97% retain main-
tenance records securely as quality records and have a procedure in place to ensure
that the maintenance scheme is reviewed periodically by a designated AP Steriliz-
ers, as recommended in the existing guidance. The maintenance scheme, including
procedures and records, is reviewed periodically by a designated person in 88% of
centres. These findings demonstrate that a very high standard of maintenance is being achieved.

Maintenance of small or benchtop sterilizers

Responsibility for the maintenance of small or benchtop vacuum and air displacement sterilizers is assigned to suitably qualified personnel in all (100%) centres (see Question 5) where this equipment is used. All of those centres using air displacement small or benchtop sterilizers retain maintenance records securely as part of the quality system, while only 67% document the procedure for maintenance tasks and the frequency at which they are carried out. Related to this 67% of centres have procedures in place to ensure that a sterilizer is not used until any required maintenance and revalidation is conducted. This demonstrates limitations in the management of the equipment and illustrates the need for further guidance in this area to ensure vigorous implementation of the quality system.

Validation

Almost all the centres (97%) assign periodic testing, maintenance and validation to a qualified test or maintenance person. However, only 77% fully document their validation procedures, recording details of the tests and checks to be carried out and the frequency with which they should be and are performed. While 97% of all centres carry out an annual revalidation, what constitutes ‘validation’ varies across the centres. For example, about 3% (one centre) do not carry out an automatic control test or a thermometric test for small and large loads on revalidation, while only 72% have an effective system in place for calibrating the indicating and recording instruments used to validate and routinely test sterilizers. This is an important area for potential further risk reduction and is emphasised in the new CFPP guidance. The new guidance offers choice as to the method used to support the validation process but strongly emphasises and defines the key elements within validation. Working with the Institute of Decontamination Sciences (IDSc), DH has also more clearly allocated the roles of persons/staff within the overall process of maintenance, periodic testing and formal validation.

At the time of the initial survey, guidance in this area was provided by HTM 2010 and the Medicines and Healthcare products Regulatory Agency (MHRA) guidance in relation to benchtop sterilizers. The need to develop guidance further was a motivating factor for the generation of CFPP 01-01.
8. Are standards of validation, testing and record keeping in SSDs adequate to support robust audit and provide a platform for further development?

Porous load sterilizers

The analysis has already established that the majority of centres (97%) carry out an annual revalidation exercise, and that they assign periodic testing, maintenance and validation to a qualified test or maintenance person. The responsibility for determining the necessity and extent of repeating elements of performance validation is assigned to a designated person with appropriate training and qualifications in 82% of centres. For all of the centres this work is assigned, including performance requalification, to a suitably qualified test person.

These findings are in keeping with the validation figures in Question 7, where 97% of centres have a qualified test or maintenance person assigned to periodic testing, maintenance and validation. It would appear that the repeating elements of ongoing performance validation processes are almost always assigned to a designated person with appropriate training and qualifications.

Where a review of records from routine monitoring, periodic testing and performance requalification indicates the need for recommissioning, only 55% of centres subsequently carry out this action. Of the centres surveyed, only 44% were correctly assigning revalidation to a designated person with appropriate qualification and experience. These findings demonstrate a need for further guidance on roles and responsibilities.

The correct calibration of instruments used in the testing and validation of steam sterilization equipment is a key issue. Incorrectly calibrated instrumentation may result in errors in the validation of sterilizers, compromising the validity of the whole process. Accordingly, the use of a systems approach to calibration is recommended in the extant guidance, though this predates recent refinements. When these refinements are taken into account, 72% of centres would still be classified as having an acceptable approach. In order to build on this position, systems for validation instrument calibration are described and strengthened in CFPP 01-01 B.
**Washer-disinfectors**

In almost all centres (97%), the person carrying out the yearly revalidation tests is a qualified test person (AP Sterilizers), with sufficient relevant experience and appropriate training to enable him or her to maintain and test washer-disinfectors. That same person carries out the yearly revalidation tests to a satisfactory standard and reviews the maintenance records and log books to ensure that they are satisfactory.

There were revalidation reports, documenting the test instrumentation used and a calibration certificate traceable to national standards, in 94% of centres. In each case the test instrumentation had a current calibration certificate at the time of washer-disinfector revalidation. It would appear that the results for washer-disinfectors are slightly better than those for sterilizers. CFPP 01-01 recommends that the results from this work be reported to the Head of Decontamination and to the proposed new role of Surgical Instruments Manager.

**Note**

These findings suggest that guidance and audit of validation, testing and record keeping in SSDs need strengthening. This issue is a focus in the new CFPP 01-01. Clearer allocation of duties to key members of staff is seen as a way of improving results in this area.

9. Have centres that offer paediatric services put safeguards in place to minimise the risk of young patients presenting for surgery being exposed to the CJD and vCJD infective agent, particularly those born since January 1997?

Of the centres offering paediatric services, only 26% have a comprehensive strategy in place to adhere to NICE guidance on separate sets of what might be called ‘high-risk tissue surgery instruments’ for children born since January 1997; 24% of centres have a strategy for managing a separate pool of neurological instruments; 18% have a separate pool of neuroendoscopes; and 36% have a separate pool of posterior ophthalmic instruments. In addition, 74% can identify instrument sets used on a non-exclusive basis with children born post-January 1997 and 11% can identify individual instruments used in instrument sets and supplementary instrument sets. However, no centre outside the pilots is achieving full risk control with respect to vCJD transmission for children born after January 1997.

Although some pilot centres such as Newcastle Teaching Hospitals NHST and GOSH have made good progress in this area, the overall results show a need for
further guidance on implementing NICE IPG 196 (2006). At present the risk-reduction targets, set as part of NICE IPG 196 (2006), are not being achieved.

10. As effectiveness of steam sterilization is dependent upon the cleanliness of the instruments prior to sterilization, have cleaning practices been effectively implemented?

Manual cleaning practices

While automated cleaning methods are preferable to manual cleaning and are dominant in the acute sector, there are times when manual cleaning is necessary, either in addition to an automated process or, in exceptional circumstances, when a piece of equipment cannot be cleaned using an automated process. The survey shows that 84% of centres have documented criteria for choosing when to undertake manual washing, 93% have a protocol in place and 97% of staff engaged in washing and disinfection are specifically trained in this process.

One or more dedicated sinks for instrument cleaning are available in 84% of centres. The sinks are included as a positive finding in this survey report only where they are properly designed and equipped for instrument washing.

As to whether or not instruments or equipment are cleaned according to current guidance, just 10% confirm that cleaning is carried out under running water rather than via immersion, and only 12% have extract ventilation to minimise aerosol dispersion during the manual cleaning process.

The cleaning process is of particular importance where instruments have lumens, and therefore an enhanced potential for biomolecular contamination. In these instances the use of carefully-selected detergents and appropriate equipment is of particular importance. In 65% of centres, a specialised instrument detergent is used for additional or specialised cleaning of instruments which have lumens. Of the centres surveyed, 85% use a soft bristle rather than a potentially damaging wire brush or pipe cleaner with these instruments. All centres process instruments with lumens in a washer-disinfector following manual cleaning. No centres use wire scourers on the outside of instruments, and 24% use nylon scourers.

Of the centres, 80% consistently use the same detergent throughout their decontamination facilities and 93% of these confirm that the concentration used is as specified by the manufacturer and the concentration level is measured by protocol in 86% of cases. However, only 80% of centres have calibrated the volume
of water used in their sinks. Where this is done and the protocol is applied to the volume of detergent used, then a reliable dilution factor will be obtained. Further, only 40% specify the water temperature for the commencement of manual cleaning. The current technologies are validated by a visual instrument inspection process and thus are optimised to the appearance of cleanliness.

The planned shift to an emphasis on protein removal and related testing will affect this area greatly – evidence from studies at Porton Down showed no correlation between the visual appearance of instruments and the extent of protein contamination. There are also special problems in respect of determining the cleanliness status of instrument lumens. Here visual inspection is difficult and at least some of the new technology tests are unlikely to be effective.

For instruments which cannot be immersed or satisfactorily wetted in a stream of water because of their design or construction – which occurs in 90% of centres – practice is variable. 96% report thoroughly wiping instruments with a clean damp cloth, and 45% with an alcohol wipe. It is not clear whether the alcohol wipe is in addition to the wipe with a damp cloth.

### Hand-washing

The intention is that a separate basin always be provided for hand washing, but the survey’s environmental findings (see Question 10) show that only 36% of centres have dedicated wash-hand basins sited near enough to the dedicated instrument cleaning sinks that staff can readily wash their hands between and after processes. Equally, a fitting is only seen as a wash-hand basin when no plug is present and the taps are capable of elbow/arm/foot or remote operation.

### Washer-disinfectors

Data analysis in previous questions has covered maintenance, testing, validation and record keeping. The focus of this particular question in relation to washer-disinfectors is on the loading of the surgical instruments. Validation tests are undertaken in 56% of centres to determine the most effective locations for placing soiled instruments in washer-disinfectors. The purpose of such tests is to improve or maintain the cleaning process.
Drying

While all centres (100%) dry instruments following manual cleaning, the drying method varies considerably: 63% dry the instruments manually, 53% with a paper towel, 39% with hot air, 30% with an alcohol wipe and 13% leave them to dry in the atmosphere. These figures indicate that some centres use more than one of the methods listed above.

Inspection of the cleaning process

Daily inspection or review of the cleaning process, including the visual inspection of instruments, is in place in 70% of centres.

All centres (100%) inspect each instrument following cleaning and in 86% of cases, inspections are carried out by someone other than the designated person in charge of cleaning. A record of who washed the instruments is kept at 67% of centres.

Monitoring cleaning efficacy

There appears to be some confusion as to what quantitative and non-quantitative tests are for cleaning, with 65% of centres stating that they use quantitative or semi-quantitative test methods, and 57% stating that they use non-quantitative test methods. It is not possible from these results to determine if any centres do not use testing methods at all.

65% use quantitative or semi-quantitative test methods

51% use semi-quantitative tests (ninhydrin or biuret)

24% use more nearly quantitative tests (OPA)

81% use weekly residual protein test

57% use non-quantitative methods

Staff training

The survey shows that 82.5% of operator staff are trained and skilled in the tasks which they are expected to perform. However, some aspects of training are better
than others. For example, while 97% of staff who carry out manual washing are trained in the activity, only 70% have taken part in a training programme leading to a formal qualification.

11. Is the physical working environment within SSDs adequate to support long-term improvements to their services?

DH provides guidance on the working environment in Health Building Note (HBN) 13 and the questions within the survey are largely based on HBN 13 guidance. Most centres achieved more than 80% for standards related to the SSD environment, which is a very positive outcome. Where standards are less satisfactory, a number of themes emerge, including:

- a lack of materials stores and ill-used sterile stores;
- poor compliance with controlled ventilation standards;
- a lack of appropriate wash-hand basins;
- a lack of testing and calibration equipment for inspection equipment;
- variances in microbiological sampling procedures and documentation; and
- a lack of defined procurement policies.

**Materials and sterile goods storage**

Sterile products should be stored in a suitable environment, preferably a dedicated store. Even though 76% of centres surveyed have a sterile goods store, they often use these to store products other than processed goods. For example, 20% use them for laundered textiles, 40% for detergents and chemicals and 24% for replacement instruments. This also leaves a number of centres (24%) with no dedicated sterile products storage area.

In addition, 77% have dedicated materials stores for material used in decontamination and these are equipped with interlocking doors. However, the additional requirements recommended in HBN 13 are not met by 23% of these storage facilities.
**Gowning area**

The standard for SSDs is to have a gowning area within the washroom. When asked if they had a gowning area, only 36% of centres responded positively. This survey is unable to establish whether the centres have a gowning area or an alternative gowning room.

**Ventilation**

The survey sought to identify the air pressure regimes present in SSDs. A few centres responded that they had both positive and negative pressure in the same area, probably reflecting the use of a flow-through clean to dirty approach.

Taking account of the above uncertainties the survey shows that only 35% of sterile goods stores have positive air pressure.

Raw materials storage is present in 77% of centres, where a positive pressure regime is applied for goods protection, whilst 31% of centres have negative pressure storage facilities to restrain fumes and other forms of leakage. The survey shows that 67% of inspection and preparation for wrapping (IAP) rooms are mechanically ventilated under reduced pressure. The concern here is that 33% of IAPs are not mechanically ventilated.

In relation to wash areas, 77% register negative pressure. However, the survey is unable to establish what the remaining 23% have and can only assume that they have no mechanical ventilation. Sterilizer loading areas have positive pressure in 33% of centres.

These findings suggest that there is a need to strengthen and clarify guidance in this area.

**Wash-hand basins**

The survey sought to identify whether particular areas of SSDs had wash-hand basins. The findings identified that only 38% of goods reception areas have a wash-hand basin. Washrooms have wash-hand basins in 36% of centres, but only 76% of these are compliant with wash-hand basin specifications.
Surgical instrument test equipment including electrical safety

The availability of equipment for testing surgical instruments is poor. Just 26% of centres surveyed have a diathermy insulation tester, only 50% of which show evidence of calibration. An electrical continuity tester is available in only 34% of centres, and of these only 70% show evidence of calibration. Only 57% have a compressed air source for testing power tools, with only 40% having evidence of calibration.

These findings suggest that a marked improvement is required in this area.

Maintenance of inspection equipment could also be improved, with only 53% of centres having a formal procedure for lighting maintenance and 76% having a formal procedure for heat sealers’ maintenance. It may be that the procedures are in place but are not documented.

Infection control

Environmental microbiological sampling takes place in 74% of centres. However, only 67% have a procedure in place for dealing with a test failure. There is only limited guidance within HBN 13, HTM 03-01 or from MHRA for this area. However, notified bodies are applying the MDD standard for registered units. This is an important area for future improvement.

Procurement

Clinical teams, infection control teams and SSD personnel are key to the buying process. In 73% of centres, a named individual prepares pre-purchase specifications and the same number (73%) review them to check that the items are compatible with existing equipment, processes, cleaning chemicals and procedures. User and decontamination team liaison particularly designed to ensure that equipment can be reprocessed is in place in 75% of centres.

Infection control teams are involved in the instrument procurement process in 43% of centres, and 24% of these also involve an AP. If an item cannot be cleaned, disinfected or sterilized with existing equipment, 40% of centres have a written document identifying an alternative process. The availability of decontamination information prior to purchase is determined by 62% of centres.
Significant improvements need to be made in order to involve all relevant parties in the purchase of surgical equipment.

12. Are staff involved in decontamination appropriately trained?

The results for staff training give a mixed picture with regard to each specific area of decontamination training. The survey identifies that 82.5% of operational staff are appropriately trained and skilled for the tasks which they are expected to perform, and that this training is recorded. Results confirm that for 93% of centres, there is a procedure in place which ensures that staff undertaking reprocessing are trained on handling new items. All staff (100%) are trained to ensure that decontamination is carried out to manufacturers’ instructions, 97% of which is documented.

A periodic review of skills takes place in 97% of centres, with 93% documenting the review and any training required. While training is clearly taking place, only 72% of centres have implemented a dedicated training programme. Up to 76% of centres report quality issues which they consider to be closely related to a requirement that staff be trained adequately in the application of quality systems based on international standards. Staff lack formal qualifications in much of this area.
4.0 Discussion and conclusions

The survey findings provide a sound baseline for any follow-up research. They can be used to determine:

- Whether standards in decontamination quality systems in high-risk tissue centres have continued to improve, stayed static or declined compared to a baseline established in 1999.
- How well developed decontamination quality systems are, immediately prior to the publication but after piloting of CFPP 01-01 Parts A, B, C, D and, therefore, the ability of the centres in question to implement the detailed requirements of NICE IPG 196 (2006) guidance.

4.1 The surveyed centres’ performance

The NDS 2008/10 indicates that the majority of centres are implementing reprocessed surgical instrument quality system guidance and that engagement with the guidance is such that a positive impact on protein removal and prion infectivity reduction would be expected. Brief experimentation conducted as part of a preliminary study in advance of a new pilot at Southampton University Hospital has tended to support this view. When the quality system requirement and manufacturer’s instructions were fully and properly applied to specified washer-disinfectors it was found that for hydrophilic proteins a removal ratio of 104 was obtained. In similar experiments with hydrophobic examples (fibrinogen) the effects were however less pronounced, with a removal factor of about 100 being observed.

However, the evidence also suggests that certain aspects of decontamination guidance are better followed than others, and that further development of the guidance is needed to raise standards in all of the recommended areas.

4.11 Implementation of NICE IPG 196 (2006) guidance

Implementation of NICE IPG 196 (2006) guidance has not progressed as rapidly or fully as had been expected. It is likely that the potential reduction in prion transmission risk offered by this guidance is not yet being fully realised in hospitals in England, so that patients remain at a higher risk than necessary of being exposed
to the CJD or vCJD infective agent from unsuspected carriers. For many centres, key measures such as the reduced migration of instruments between sets and the removal of supplementary instruments are not yet in place. The track-and-trace technologies which enable single instruments to be tracked are only implemented and working in a small number of centres. Set-based tracking is, however, almost universally applied.

The paediatric risk-reduction recommendations in NICE IPG 196 (2006) have been particularly poorly implemented, despite the emphasis on the importance of these measures. However, work in the pilot centres supported by DH is leading to a much better understanding of how to implement the NICE IPG 196 (2006) recommendations; business planning and procurement strategies have been developed, for example. The pilots have also successfully linked the new instruments for use with young children to their clinical programmes and to single-instrument tracking. If copied on a national basis, it is likely that the current poor implementation position could be rapidly improved.

The letters from CMO in support of NICE IPG 196 (2006) guidance seem to have had a positive impact on the implementation of the risk-reduction measures.

4.12 Reuse of single-use instruments

The survey shows qualified evidence that the reuse of single-use instruments does occur though at a low rate.

4.13 Implementation of ACDP-TSE RM guidance

The guidance from the ACDP-TSE Working Group on control of surgical infection transmission risk from at-risk patients is reasonably well implemented, although some of the more specific recommendations have not yet seen full application. New guidance from the ophthalmic working group of ACDP-TSE is available as Annex L from the Advisory Committee website.

4.14 External decontamination services

The survey provides limited evidence, from a small number of neurosurgical centres where outside commercial contracts are used for decontamination of
surgical instruments that such suppliers do not always make distinctions in terms of the management of instruments which are used with high prion transmission risk tissues. This leads to difficulties with the implementation of NICE IPG 196 guidance.

Helpfully, the Birmingham Children’s Hospital pilot is being conducted with an external supplier and this company has agreed to assist both the hospital and DH with a study in this area.

4.15 Adherence to quality standards

The analysis related to decontamination process quality systems, derived from BSi/EN/ISO quality standards and their implementation, shows strong performance in this area. The implication is that procedures and controls are sufficiently robust in most centres to permit a round of further improvement and the eventual implementation of the new anti-prion decontamination technologies reported on in the ESAC-Pr New Technologies Working Group Report on Prion Inactivating Agents (August 2008).

4.16 Operational practices

Consistent and well-designed operational practices are a key aspect of decontamination and crucial to maintaining a continuously high quality of product output. The majority of centres have good controls and practices in place and many show examples of best practice.

4.17 Safety testing equipment

There are real concerns about instrument and safety device test equipment, used to ensure that surgical instruments are safe for use, particularly in respect of what may be severe electrical hazards. The lack of insulation testing equipment for diathermy is a matter for particular concern, as are a number of other detailed findings in this area. The focus of CFPP 01-01 on this safety issue will be improved and a professional letter to heads of surgical and decontamination departments is recommended.
4.18 Environment for decontamination

The environment in which decontamination and instrument management are carried out has not improved as rapidly as the equipment itself. Many centres fail to provide such simple key facilities as wash-hand basins. Room and space designation for specific tasks, particularly those related to storage, is weak. This indicates a need to modernise the guidance on the decontamination environment. Ventilation of the environment and rationale for airflow strategy are weak in many centres.

4.19 Training and management

The results on record keeping and staff training imply a good quality workforce with mostly high standards of management. The work of occupational health and human resources departments in this area appears to be strong, with evidence of safe outcomes. However, there is an identifiable absence of professional training and recognition amongst many grades of staff.

4.2 Creating a platform for new technologies

Animal assays based on the use of prion-contaminated wires suggest that the current decontamination approach is of limited value in reducing prion risks, particularly where instruments have been in contact with high-risk tissues. However, the improvements recommended in existing guidance and monitored by the NDS are intended to create sufficient strength in quality control to make the introduction of new and potentially more effective decontamination technologies a valid option. These new technologies are described in an ESAC-Pr document ‘New Technologies Working Group – Report on Prion Inactivating Agents (August 2008)’. 
5.0 Recommendations

The imperative today is to build on the sound implementation of existing guidance towards further improvement in both general and prion infection risk-reduction. To this end the recommendations are:

a. Strengthening NICE IPG 196 (2006) implementation, using evidence from the pilot sites (see CFPP 01-01 Part A) to support the provision of further guidance in CFPP 01-01. FOM analysis confirms the need for a greater emphasis on implementation of protein removal and prion risk-reduction features in decontamination;

b. Considering why trusts are not making more progress with implementing NICE IPG 196 (2006) and other prion risk-reduction guidance, to establish whether cashflow implications or other priorities may be preventing them from realising the guidance in full. DH has already completed work in this area, and the cost of implementing guidance in CFPP 01-01 has been fully researched;

c. Devising an urgent programme of improvements for equipment safety and calibration testing, with particular emphasis on diathermy;

d. Promoting a stream of further quality systems improvement from the use of EN, ISO and BSi standards through to CFPP 01-01. The report findings support the need for further operational guidance in this area;

e. Consulting with the ACDP-TSE RM sub-group on enhancing the use of its guidance, now that good data on implementation has been established. The inclusion of references to ACDP-TSE RM guidance in CFPP 01-01 for general and ophthalmic surgery and in CFPP 01-06 for non-sterile endoscopy was a recommended priority of this report;

f. Optimising the use of washer-disinfectors. The validity of proposals for new research on protein removal in washing processes is well-supported by current quality systems implementation, making washer-disinfectors optimisation both feasible and worthwhile in the working environment;

g. Introducing interdictive prion control measures, designed to block completely the transmission of prions, as soon as the scientific evidence supports their
selection and incorporation. Appropriate heed must, however, be paid to staff and patient safety in the selection of candidate technologies. The need for care over residual toxicity is mentioned within the guidance;

h. Introducing local self-audit programmes in the centres, particularly in those where implementation of NICE and ACDP guidance is being pursued. This programme will be conducted by an independent learned body with DH support in results analysis;

i. Repeating the survey in two or more years' time to examine the effect of implementing CFPP 01-01 is advised by learned bodies and is under consideration by DH;

j. Developing better guidance on the physical environment for ventilation of decontamination facilities by the provision of further design guidance;

k. Advocating such simple improvements as the better provision of wash-hand basins and operational protocols in order to raise hygiene standards in inspection rooms within decontamination units;

l. Strengthening surgical instrument management, with the introduction in CFPP 01-01 of the role of Surgical Instruments Manager within all surgical centres in acute care, together with better protocols for implementation and audit. Loan set instruments may also be a factor here and the use of audit for reliable tracing is recommended. In the case of high-risk procedures a link to patient identity appears necessary and would fit with the position taken by ACDP-TSE RM. The systems provided by Connecting for Health and Coding for Success are suitable for this purpose;

m. Introducing measures to reduce the likelihood of single-use instrument reuse. A need for enhanced guidance on the disposal of single-use instruments is a key issue raised by several groups co-operating in the survey;

n. Reviewing single-instrument tracking and set structure. A series of options are described fully in CFPP 01-01 A; and

o. Reviewing commercial contract terms to ensure that compliance with current decontamination guidance, such as that contained in NICE IPG 196 (2006), CFPP 01-01 and provided by ACDP-TSE RM, is reflected in arrangements for external surgical instrument decontamination services.
6.0 References

6.1 DH standards, guidance, reports and professional letters


Department of Health (2003) Transmissible spongiform encephalopathy agents: safe working and the prevention of infection – Guidance from the Advisory Committee on Dangerous Pathogens and the Spongiform Encephalopathy Advisory Committee. DH.
http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm


6.2 NICE Guidance


6.3 Department of Health Building Notes, Technical Memoranda and facilities’ guidance


Department of Health (2007) HTM 03-01: Heating and ventilation systems: Specialised ventilation for healthcare premises. Part B – Operational management and
performance verification.
https://publications.spaceforhealth.nhs.uk


https://publications.spaceforhealth.nhs.uk

https://publications.spaceforhealth.nhs.uk

6.4 Medical devices directives and regulations


6.5 British, European and international standards

**Note**
These were the extant standards at the time of the 2008 survey. Since then, some may have been superseded or withdrawn.


6.6 Health Service Circulars


6.7 Acts and Regulations


6.8 Other publications


Annex 1: Figure of merit analysis method

1. Introduction

Figure of merit (FOM) is the system used to score the collected survey data to provide a basis for further analysis.

FOM uses weighting factors to establish the relative importance of each item under review. In the NDS 2008/10, each survey question was assigned to the appropriate Quality System Category. A special sub-group of ESAC-Pr weighted each of these Quality System Categories on a scale of 1 to 5 (5 being the highest), according to their relative importance in terms of prion removal and deactivation.

The FOM (%) Score and FOM Rating are two key outputs from the FOM scoring system:

- The FOM (%) Score provides a measure of the merit (or benefit) suggested by each survey answer. A score of 100% for a specific answer indicates that the maximum merit (or benefit) was achieved for that question or point. However, it should not be possible for a site to score 100% over the complete survey. This is because of the options available for decontamination practice at the time of the survey, the way the survey questionnaire is structured and the fact that two of the negative numerical questions have a maximum possible score of 50%. A score in the region of 87% should be considered as the effective maximum possible value for the 2008 survey. In a repeat survey after the introduction of CFPP 01-01 it should become possible for excellent service providers to reach figures above 90%.

- The FOM Rating grades each FOM (%) Score using an A to E scale, intended to assist with the interpretation and comparison of the survey results. As discussed above, the A rating is not achievable within the present survey but may be attainable in the repeat exercise.
2. Scope of answers scored by FOM

All of the answers collected during the survey were included in the scoring process except for the following:

2.1 Answers to questions with an FOM weighting of 1 have not been scored and are excluded from trust reports

DH considers all survey questions assigned a Quality System Category weighting of 1 to be of minimal relevance in terms of prion removal and deactivation. Scores are not calculated for these questions, as attempting to do so would produce both numerator and denominator values of zero in the FOM (%) Score calculation and therefore an undefined result. However, many of these considerations are of key concern in the conventional business of cleaning and sterilization. To this end, three analysis questions related to cleaning practices, staff training and working environment have been included in this report.

In the current survey, 277 questions have a weighting of 1. A further 10 questions remain unweighted, because they could not be mapped to a Quality System Category in a valid way.

These questions are not included in the trust reports but their exclusion does not affect the scores achieved.

2.2 Answers to questions not scored for reasons other than FOM weighting but which are included in trust reports

The following types of question and answer are included in the trust reports but are not scored:

Text/date questions – questions requiring text or date answers;

Object numerical questions – questions that are numerical and object-related (for example, ‘how many sinks do you have?’);

Neutral questions – questions for which it is not clear whether, for example, a ‘yes’ answer should be scored as positive or negative;
Questions answered ‘N/A’ – where a researcher has recorded that a question is not applicable to the site being examined.

3. Calculating the Figure of Merit

3.1 FOM Rating

The FOM Rating grades each FOM (%) Score using an A to E scale and is intended to assist with the interpretation and comparison of the survey results. The FOM Rating is derived from this table:

<table>
<thead>
<tr>
<th>FOM (%) score</th>
<th>FOM rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>88 or above</td>
<td>A</td>
</tr>
<tr>
<td>72 – 87</td>
<td>B</td>
</tr>
<tr>
<td>60 – 71</td>
<td>C</td>
</tr>
<tr>
<td>49 – 59</td>
<td>D</td>
</tr>
<tr>
<td>Below 49</td>
<td>E</td>
</tr>
</tbody>
</table>

3.2 FOM (%) Score

The FOM (%) Score provides a measure of the merit (or benefit) suggested by each survey answer. A score of 100% indicates that the maximum merit (or benefit) was achieved.

The FOM (%) Score is calculated using this formula:

$$\text{FOM (\%)} = \left[ \frac{\text{FOM Score}}{\text{Maximum Weighted Score}} \right] \times 100$$

3.3 Actual FOM Score

The Actual FOM Score is the actual score achieved by a survey answer expressed as a decimal fraction after applying the relevant weighting factor. The range of possible values is between zero and the Maximum Weighted Score.
The Actual FOM Score is calculated using this formula:

\[
\text{Actual FOM Score} = \text{Rescaled Score} \times \text{Maximum Weighted Score}
\]

3.4 Maximum Weighted Score

The Maximum Weighted Score is the maximum score achievable for a survey answer expressed as a decimal fraction after applying the relevant weighting factor. It therefore determines the maximum value that can be achieved for the Actual FOM Score.

The ‘Maximum Weighted Score’ is calculated using this formula:

\[
\text{Maximum Weighted Score} = \frac{\text{Weighting factor} - 1}{4}
\]

3.5 Initial Score

The Initial Score is the score recorded for each survey answer before a weighting factor is applied and before conversion of the score to a decimal fraction.

3.6 Rescaled Score

The Rescaled Score is the Initial Score converted to a decimal fraction scale but before a weighting factor is applied.

The tables that follow translate each possible binary and numerical survey answer to an Initial Score.

The Rescaled Score is calculated using this formula:

\[
\text{Rescaled Score} = \frac{x - x_{\text{min}}}{x_{\text{max}} - x_{\text{min}}}
\]

where \(x\) is the Initial Score, \(x_{\text{min}}\) and \(x_{\text{max}}\) respectively the minimum and maximum possible values for the Initial Score.
### 3.7 Scoring the binary questions

Binary questions scored as a positive (‘yes’ is the correct/desired answer):

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
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<td>0.00</td>
<td>1.00</td>
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<td>0.00</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>N/A</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>&lt;blank&gt;</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Binary questions scored as negative (‘no’ is the correct/desired answer):

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>No</td>
<td>1.00</td>
<td>0.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>N/A</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>&lt;blank&gt;</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

### 3.8 Scoring numerical questions

Numerical questions with ‘1 to 5’ scale scored as a positive (higher is better):

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
<tr>
<td>2</td>
<td>2.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.25</td>
</tr>
<tr>
<td>3</td>
<td>3.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.50</td>
</tr>
<tr>
<td>4</td>
<td>4.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.75</td>
</tr>
<tr>
<td>5</td>
<td>5.00</td>
<td>1.00</td>
<td>5.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;blank&gt;</td>
<td>0.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>
Numerical questions with a ‘1 to 5’ scale scored as negative (lower is better):

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5.00</td>
<td>1.00</td>
<td>5.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>0.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
<tr>
<td>3</td>
<td>0.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
<tr>
<td>4</td>
<td>0.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
<tr>
<td>5</td>
<td>0.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
<tr>
<td>&lt;blank&gt;</td>
<td>0.00</td>
<td>1.00</td>
<td>5.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Note
Where a question uses a ‘1 to 5’ scale, 5 scores as ‘high/always’ and 1 scores as ‘low/not at all’.

Numerical questions with a ‘1 to 10’ scale scored as positive:

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.10</td>
</tr>
<tr>
<td>2</td>
<td>3.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.20</td>
</tr>
<tr>
<td>3</td>
<td>4.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.30</td>
</tr>
<tr>
<td>4</td>
<td>5.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.40</td>
</tr>
<tr>
<td>5</td>
<td>6.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.50</td>
</tr>
<tr>
<td>6</td>
<td>7.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.60</td>
</tr>
<tr>
<td>7</td>
<td>8.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.70</td>
</tr>
<tr>
<td>8</td>
<td>9.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.80</td>
</tr>
<tr>
<td>9</td>
<td>10.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.90</td>
</tr>
<tr>
<td>10</td>
<td>11.00</td>
<td>1.00</td>
<td>11.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;blank&gt;</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>
Numerical questions ‘1 to 10’ scale scored as negative:

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.50</td>
</tr>
<tr>
<td>2</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>3</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>4</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>5</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>6</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>7</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>8</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>9</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>10</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
<tr>
<td>&lt;blank&gt;</td>
<td>0.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Note
The current survey questionnaire contains only four numerical questions where a scale of 1 to 10 is used. Of these, two score as positive and two as negative.

The wording of the questions using the ‘1 to 10’ scale refers to ‘10 being 100%’ but does not indicate whether a 1 is to be interpreted as ‘zero/not at all’, as would be the case had the ‘1 to 5’ scale been used.

In the table for questions scored as positive, the Initial Score and Max Score have been incremented by 1 to produce a Rescaled Score which more closely reflects the percentage scale implied by the wording of these questions.

Caveat: Where a researcher recorded a binary Yes answer to this type of numerical question, the system will amend the answer to a numerical value of 6 (refer to section 6 of this annex for information on data conversion issues) and calculate the Rescaled Score as follows:

<table>
<thead>
<tr>
<th>Original answer</th>
<th>Amended answer</th>
<th>Initial score</th>
<th>Min score</th>
<th>Max score</th>
<th>Rescaled score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>6</td>
<td>6.00</td>
<td>1.00</td>
<td>11.00</td>
<td>0.50</td>
</tr>
</tbody>
</table>

For the questions scored as negative, only the minimum answer value (1) is allocated a non-zero score. However, given the ambiguity in the scale being used for
these questions, DH has decided to allocate a Rescaled Score of 0.5 rather than 1.0 where the Initial Score is 1.

A value of 0.5 is consistent with the score that would be achieved had a binary answer been converted to a numerical.

The relevant survey questions are both in the ‘Vigilance’ survey category:

439(a)
How frequently, as a % of sets processed, are sets returned for reprocessing found to have instruments missing? Please indicate the percentage by selecting the appropriate number from the drop-down box (10 being 100%)

439(b)
How frequently, as a % of sets processed, are sets returned for reprocessing found to have instruments which are defective and must be replaced? Please indicate the percentage by selecting the appropriate number from the drop-down box (10 being 100%)

4. Quality System Categories

DH has agreed a set of Quality System Categories to facilitate the analysis of the survey results and has assigned each survey question to an appropriate category.

Weighting factors are scaled from 1 to 5. A weighting of 1 indicates that a survey question is of minimal relevance in terms of prion removal and deactivation. A weighting of 5 indicates that a survey question is of the highest relevance in these terms.
### 4.1 Quality System Categories relevant to prion removal and deactivation

<table>
<thead>
<tr>
<th>QS_ID</th>
<th>Quality System Category</th>
<th>Relevant guidance</th>
<th>Relevant EN/ISO standards</th>
<th>Weighting factor</th>
<th>No. of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HTM 01-01 A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Water quality</td>
<td>HTM 04-01</td>
<td>Water Supply BS 6700 (2006)</td>
<td>3</td>
<td>31</td>
</tr>
<tr>
<td>7</td>
<td>Inspection</td>
<td>HTM 01-01</td>
<td></td>
<td>5</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>HTM 2031</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Record keeping</td>
<td>HTM 01-01</td>
<td>Medical Devices, Quality Management Systems: BS EN ISO 13485 (2003)</td>
<td>5</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Record Management Code of Practice (2006)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Coding For Success (GS1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>MDD Essential Requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QS_ID</td>
<td>Quality System Category</td>
<td>Relevant guidance</td>
<td>Relevant EN/ISO standards</td>
<td>Weighting factor</td>
<td>No. of questions</td>
</tr>
<tr>
<td>-------</td>
<td>--------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>14</td>
<td>Staffing / training</td>
<td>IDSc initiative IHEEM AE(D)</td>
<td>HTM 01-01 Part A, CQC MHRA notified body.</td>
<td>5</td>
<td>32</td>
</tr>
<tr>
<td>17</td>
<td>Dispatch and transport</td>
<td>Clean Waste UN 3291 Trade Barrier Regulations (2007)</td>
<td></td>
<td>2</td>
<td>44</td>
</tr>
</tbody>
</table>

Number of ‘relevant’ survey questions 723

Notes

‘No. of questions’ refers to the number of questions assigned to each Quality System Category in the NDS 2008/10.
4.2 Quality System Categories related to quality of decontamination for general patient and staff safety purposes

<table>
<thead>
<tr>
<th>QS_ID</th>
<th>Quality System Category</th>
<th>Relevant guidance</th>
<th>Relevant EN/ISO standards</th>
<th>Weighting factor</th>
<th>No. of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Environmental control</td>
<td>HBN 13</td>
<td>BS EN ISO 14644</td>
<td>1</td>
<td>188</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CFPP 01-01 B</td>
<td>BS 5925 (1991)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Staffing control</td>
<td>HTM 01-01 Part A</td>
<td></td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>Personal hygiene</td>
<td>HCAI 08 Code of Practice</td>
<td></td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>4</td>
<td>Personnel / staff safety</td>
<td>Health &amp; Safety at Work Act 1974</td>
<td></td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>8</td>
<td>Packaging</td>
<td>HTM 01-01 Parts A and B.</td>
<td>BS EN ISO 11607 (2006)</td>
<td>1</td>
<td>22</td>
</tr>
<tr>
<td>13</td>
<td>Microbiological supervision</td>
<td>HTM 01-01 Part A,</td>
<td></td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HCAI 08 Code of Practice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Disposal</td>
<td>HTM 01-01 Part A</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Unmapped questions</td>
<td></td>
<td></td>
<td>-</td>
<td>10</td>
</tr>
</tbody>
</table>

Number of ‘non-relevant’ survey questions 287
5. Type of question – positive, negative and neutral

The ‘Question type’ determines the scoring method applied to each survey answer.

<table>
<thead>
<tr>
<th>Question type</th>
<th>Scoring method</th>
<th>No. of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>A ‘yes’ answer is scored as a positive response and a ‘no’ answer is scored as a negative response</td>
<td>896</td>
</tr>
<tr>
<td>Negative</td>
<td>A ‘no’ answer is scored as a positive response and a ‘yes’ answer is scored as a negative response</td>
<td>100</td>
</tr>
<tr>
<td>Neutral</td>
<td>Answers are indeterminate in terms of their perceived merit and therefore are not scored</td>
<td>14</td>
</tr>
</tbody>
</table>

Number of survey questions: 1010

6. Data conversion issues

Due to weak data type enforcement in the data capture application, it was possible for a researcher to record a binary answer against a numerical question and a numerical answer against a binary question. In total, 1,506 answers required conversion (see table in section 6.6, audit keys 6 to 15) out of a total of 50,496.

DH devised the following decision tables to determine the appropriate method of conversion for each possible case.

6.1 Conversion of binary answers to numerical answers

Where a researcher recorded a binary answer to a non object-related numerical question, the system amends the answer in accordance with the following decision table:

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>Answer is amended to:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>where scale = ‘1 to 5’</td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>Not applicable</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
</tr>
<tr>
<td>Not available</td>
<td>1</td>
</tr>
<tr>
<td>‘See comment’</td>
<td>1</td>
</tr>
</tbody>
</table>
6.2 Conversion of numerical answers to binary answers

Where a researcher recorded a numerical answer to a binary question, the system amends the answer in accordance with the following decision table:

<table>
<thead>
<tr>
<th>Survey answer</th>
<th>converted to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>&gt; 1</td>
<td>Yes</td>
</tr>
</tbody>
</table>

6.3 Normalisation of ‘not applicable’ answers

Where a researcher answered no more than one question in a particular survey category the system enters ‘not applicable’ against all of the unanswered questions in that survey category. This is done so that non-relevant categories are removed from the scoring process for each site.

The following table contains a record for the NDS 2008–2010 of all ‘not applicable’ records entered by the system:

<table>
<thead>
<tr>
<th>Survey category</th>
<th>Category type</th>
<th>No. of sites</th>
<th>Total ‘N/A’ records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport system</td>
<td>SSD</td>
<td>1</td>
<td>43</td>
</tr>
<tr>
<td>Other sterilizer</td>
<td>ENG</td>
<td>19</td>
<td>796</td>
</tr>
<tr>
<td>Vacuum bench</td>
<td>ENG</td>
<td>25</td>
<td>1,573</td>
</tr>
<tr>
<td>Local clinical reprocessing</td>
<td>ENG</td>
<td>20</td>
<td>538</td>
</tr>
<tr>
<td>Bench top</td>
<td>ENG</td>
<td>23</td>
<td>1,171</td>
</tr>
<tr>
<td>Number of normalised records:</td>
<td>28</td>
<td>4,121</td>
<td></td>
</tr>
</tbody>
</table>


### 6.4 Audit table for system-generated answers

<table>
<thead>
<tr>
<th>Audit key</th>
<th>Audit subject / answers entered by system</th>
<th>No. of answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>02</td>
<td>Normalisation of scoring by entering ‘not applicable’ against all unanswered questions in ‘blank’ survey categories (<em>i.e.</em> those where no more than one answer is recorded)</td>
<td>4,121</td>
</tr>
<tr>
<td>03</td>
<td>Normalisation of scoring for additional items of equipment by entering ‘unknown’ against unanswered questions where the ‘Item no.’ is greater than 1</td>
<td>174</td>
</tr>
<tr>
<td>04</td>
<td>Normalisation of scoring for additional items of equipment by entering ‘unknown’ against unanswered questions where the ‘Item no.’ is 1</td>
<td>7</td>
</tr>
</tbody>
</table>

Number of answers entered by system 4,302

**Note**

The total number of answers recorded during the current survey was 50,496 (including the above total).  

### 6.5 Audit table for system-generated amendments to answers

<table>
<thead>
<tr>
<th>Audit key</th>
<th>Audit subject / answers amended by system</th>
<th>Refer to table</th>
<th>No. of answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Re-mapping of ‘Equipment item no.’ from 11 to 10 in ‘Porous Load’ section to correct error in previous data capture application</td>
<td>-</td>
<td>322</td>
</tr>
<tr>
<td>05</td>
<td>Removal of amended answers where amendment and original answer are identical</td>
<td>-</td>
<td>8</td>
</tr>
<tr>
<td>06</td>
<td>Binary questions – numerical answer ‘1’ converted to binary ‘No’</td>
<td>6.2</td>
<td>6</td>
</tr>
<tr>
<td>07</td>
<td>Binary Questions – numerical answer ‘&gt;1’ converted to binary ‘Yes’</td>
<td>6.2</td>
<td>79</td>
</tr>
<tr>
<td>08</td>
<td>Numerical questions (‘1 to 10’): binary answer ‘Not applicable’ converted to numerical ‘0’</td>
<td>6.1</td>
<td>20</td>
</tr>
<tr>
<td>09</td>
<td>Numerical questions (‘1 to 10’): Binary answers ‘No’, ‘Unknown’, ‘Not available’ or ‘See comment’ converted to numerical 1</td>
<td>6.1</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>Numerical questions (‘1 to 10’): binary answer ‘Yes’ converted to numerical 6</td>
<td>6.1</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>Numerical questions (‘1 to 5’): Binary answer ‘Not applicable’ converted to numerical 0</td>
<td>6.1</td>
<td>743</td>
</tr>
<tr>
<td>12</td>
<td>Numerical questions (‘1 to 5’): Binary answers ‘No’, ‘Unknown’, ‘Not available’ or ‘See Comment’ converted to numerical 1</td>
<td>6.1</td>
<td>143</td>
</tr>
<tr>
<td>13</td>
<td>Numerical questions (‘1 to 5’): binary answer ‘Yes’ converted to numerical 3</td>
<td>6.1</td>
<td>423</td>
</tr>
<tr>
<td>14</td>
<td>Object numerical questions: Binary answer (not ‘Yes’) converted to numerical 0</td>
<td>-</td>
<td>82</td>
</tr>
<tr>
<td>15</td>
<td>Object numerical questions: binary answer ‘Yes’ converted to numerical 1</td>
<td>-</td>
<td>4</td>
</tr>
</tbody>
</table>

Number of answers amended by system: 1836
6.6 Audit table for all recorded survey answers

<table>
<thead>
<tr>
<th>Audit subject – survey answers</th>
<th>No. of answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of recorded survey answers</td>
<td>50,496</td>
</tr>
<tr>
<td>less ‘irrelevant’ answers</td>
<td>(9,814)</td>
</tr>
<tr>
<td>No. of ‘relevant’ answers</td>
<td>40,682</td>
</tr>
<tr>
<td>‘Relevant’ answers not scored:</td>
<td></td>
</tr>
<tr>
<td>‘text / date’ answers</td>
<td>(265)</td>
</tr>
<tr>
<td>‘object numerical’ answers</td>
<td>(150)</td>
</tr>
<tr>
<td>‘neutral’ answers</td>
<td>(1,093)</td>
</tr>
<tr>
<td>‘not applicable’ answers</td>
<td>(14,203)</td>
</tr>
<tr>
<td>less ‘relevant’ answers not scored:</td>
<td>(15,711)</td>
</tr>
<tr>
<td>Number of answers scored</td>
<td>24,971</td>
</tr>
<tr>
<td>Number of trusts surveyed</td>
<td>26</td>
</tr>
<tr>
<td>Number of sites surveyed</td>
<td>30</td>
</tr>
</tbody>
</table>

**Note**
The above figures include 83 ‘blank’ answers of which 13 (8 weighted as ‘1’ and 5 that were text answers) were not scored.